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No. 08-

IN THE

# Supreme Court of the United States

GILEAD SCIENCES, INC., *et al.*,
*Petitioners,*

v.

TRENT ST. CLARE, *et al.*,
*Respondents.*

**On Petition for a Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit**

## PETITION FOR A WRIT OF CERTIORARI

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## QUESTION PRESENTED

Whether a plaintiff in a "fraud on the market" case under Section 10(b) of the Securities Exchange Act must plead facts with sufficient particularity to support a reasonable, non-speculative belief that the plaintiff ultimately can prove loss causation.

## PARTIES TO THE PROCEEDING

Petitioners, defendants-appellees below, are Gilead Sciences, Inc., John C. Martin, John F. Milligan, Mark L. Perry, Norbert W. Bischofberger, Anthony Carraciolo and William A. Lee. The individual petitioners are current and former executive officers of Gilead Sciences, Inc. Petitioner Gilead Sciences, Inc. is a publicly traded corporation with no parent corporation, and no publicly held company owns 10% or more of its stock.

Respondents are Trent St. Clare and Terry Johnson, appellants appointed as lead plaintiffs below, purporting to act on behalf of themselves and a putative class of all persons similarly situated, consisting of purchasers of Gilead Sciences securities between July 14, 2003 and October 28, 2003. No class has been certified.

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## PETITION FOR A WRIT OF CERTIORARI

Petitioners Gilead Sciences, Inc. ("Gilead"), John C. Martin, John F. Milligan, Mark L. Perry, Norbert W. Bischofberger, Anthony Carraciolo and William A. Lee respectfully request that a writ of certiorari issue to review the judgment of the United States Court of Appeals for the Ninth Circuit in this case.

## OPINIONS BELOW

The opinion of the Ninth Circuit was entered on August 11, 2008, and is reported at 536 F.3d 1049 (9th Cir. 2008). It is included in the Appendix ("App.") at 1a-20a. The Order denying Petitioners' motion for rehearing or rehearing *en banc*, entered on October 9, 2008, is included in the Appendix at 87a-88a. The opinion and order of the United States District Court for the Northern District of California dismissing

respondents' Fourth Amended Class Action Complaint ("Fourth Amended Complaint"), was entered on May 12, 2006, and is included in the Appendix at 21a-41a. That opinion is available at 2006 WL 1320466. The opinion and order of the district court dismissing respondents' Third Amended Class Action Complaint ("Third Amended Complaint"), was entered on October 11, 2005, and is included in the Appendix at 42a-61a. The opinion and order of the United States District Court for the Northern District of California dismissing respondents' Consolidated Amended Class Action Complaint ("Amended Complaint"), was entered on January 26, 2005, and is included in the Appendix at 62a-86a.

## JURISDICTION

The court of appeals issued its opinion on August 11, 2008. Petitioners timely sought rehearing, which was denied on October 9, 2008. App. 87a-88a. On December 23, 2008, Justice Kennedy extended the time in which to file this petition to February 6, 2009. The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

## STATUTORY PROVISION INVOLVED

Section 21D of the Securities Exchange Act of 1934, 15 U.S.C. § 78u-4, was added by the Private Securities Litigation Reform Act of 1995 ("PSLRA"), Pub. L. No. 104-67, 109 Stat. 737, 747. Section 21D provides, in pertinent part, as follows:

> (b)(4) LOSS CAUSATION. In any private action arising under this chapter, the plaintiff shall have the burden of proving that the act or omission of the defendant alleged to violate this

chapter caused the loss for which the plaintiff seeks to recover damages.

## STATEMENT OF THE CASE

This case presents a split of authority concerning a question left open by this Court in *Dura Pharmaceuticals, Inc.* v. *Broudo*, 544 U.S. 336 (2005): the pleading standard for alleging "loss causation" in a claim seeking damages for securities fraud. In *Dura*, this Court made clear that under Section 10(b) and the PSLRA, a plaintiff bears the burden of proving (1) that the price decline for which damages are sought occurred *after* the alleged fraud was revealed to the market, and (2) that the losses claimed are attributable only to that fraud, and not to other potentially confounding conditions or events unrelated to the fraud. *Id.* at 342-43. This Court concluded that the complaint in *Dura* failed to articulate the required *theory* of loss causation. The Court declined the invitation of the Solicitor General in *Dura* to define the pleading standard further.

Since *Dura*, lower courts have struggled with the proper pleading standard applicable to allegations of loss causation in a securities fraud complaint. Three distinct approaches have now emerged. The Fifth and Seventh Circuits have applied the particularity requirement of Federal Rule of Civil Procedure 9(b) to such pleadings. *Tricontinental Indus., Ltd.* v. *PricewaterhouseCoopers, LLP*, 475 F.3d 824, 839 n. 10, 842-43 (7th Cir. 2007); *Catogas* v. *Cyberonics, Inc.*, 292 F. App'x 311, 312-14 (5th Cir. 2008) (per curiam). The Second, Fourth and Eighth Circuits have stopped short of expressly applying Rule 9(b), but nonetheless have required that a complaint contain "sufficient factual information to provide the 'grounds' on which the claim rests, and to raise a

right to relief above a speculative level." *Schaaf* v. *Residential Funding Corp.*, 517 F.3d 544, 549 (8th Cir.) (quotation omitted), *cert. denied*, 129 S. Ct. 222 (2008); *Lattanzio* v. *Deloitte & Touche LLP*, 476 F.3d 147, 158 (2d Cir. 2007); *Teachers' Ret. Sys.* v. *Hunter*, 477 F.3d 162, 186 (4th Cir. 2007). Collectively, these courts have not allowed securities fraud complaints to survive without factual allegations providing a concrete reasonable basis to believe that the plaintiff ultimately can prove each step in the proposed chain of causation. Instead, as contemplated by the PSLRA and this Court's pleading decisions, all five Circuits require district judges to act as gatekeepers to prevent cases from going forward to discovery on the basis of sheer speculation and lawyer's argument.

By contrast, the Ninth Circuit, in this case, adopted a standard far more lenient than any other court, requiring only that the plaintiff articulate a theory of loss causation that is not "per se implausible." App. 19a.[1] Under the Ninth Circuit's approach, the plaintiff may survive a motion to dismiss merely by *asserting* that the stock drop occurred after the fraud was revealed without having to provide any factual basis to believe that the market ever learned of the fraud, and without even suggesting any factual grounds to believe that potentially confounding causes can be isolated and controlled. In the Ninth Circuit's telling, "so long as the plaintiff alleges facts that support a theory that is not facially implausible, the court's skepticism is best reserved for later stages

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[1] *See also Metzler Inv. GmbH* v. *Corinthian Colls., Inc.*, 540 F.3d 1049, 1062 (9th Cir. 2008) (applying Rule 8 standard); *Berson* v. *Applied Signal Tech., Inc.*, 527 F.3d 982, 989 90 (9th Cir. 2008) (purporting to apply Rule 9(b) but finding loss causation allegations sufficient where they gave "notice" to defendants).

of the proceedings." *Id.* at 17a. That is, only in the Ninth Circuit are the district courts forbidden to act as gatekeepers.

This low pleading threshold threatens to undermine this Court's decision in *Dura*. As the Court recognized, the securities laws should not "permit a plaintiff 'with a largely groundless claim to simply take up the time of a number of other people, with the right to do so representing an *in terrorem* increment of the settlement value, rather than a reasonably founded hope that the [discovery] process will reveal relevant evidence.'" *Dura*, 544 U.S. at 347 (alteration in original) (quoting *Blue Chip Stamps* v. *Manor Drug Stores*, 421 U.S. 723, 741 (1975)). The Ninth Circuit's decision permits precisely that.

### A. Prescription Drug Industry Background.

Petitioner Gilead is a biopharmaceutical company that discovers, develops, and commercializes therapeutics for the care of patients with life-threatening diseases. At the relevant time, Gilead marketed six products, including Viread, a groundbreaking antiretroviral drug used to treat HIV/AIDS, first introduced in 2001. The individual petitioners were at all relevant times officers of Gilead.

FDA rules require a drug manufacturer to market a drug only for uses approved by the FDA. But federal law does not prohibit physicians from prescribing a drug for so-called "off-label" uses that have not been approved by the FDA, or from requesting information about such uses from the manufacturer.

As with all prescription drugs, demand for Viread is created when doctors prescribe the drug for patients. However, Gilead does not typically sell directly to patients or their doctors. Rather, Gilead sells to

pharmaceutical wholesalers, three of which purchase the vast majority of all domestic Viread and supply the pharmacies that fill prescriptions for the drug. Wholesalers make much of their profit by buying large quantities of a drug before an expected manufacturer's price increase and later selling the drug at the new, higher price. Respondents allege that overstocking a product at the lower price and selling at the new price is central to the wholesalers' business model.

### B. Gilead's Second And Third Quarter 2003 Earnings.

*Second Quarter 2003:* In the second quarter of 2003, anticipating a price increase for Viread, Gilead's wholesalers bought excess quantities of the drug, resulting in larger than normal Viread inventory levels by the end of the quarter. Plaintiffs do not allege that Gilead knew the precise amount that the inventory levels increased during the quarter; Gilead did not have access to information regarding its wholesalers' inventory levels. Understanding the difference between revenues generated by filling prescriptions (demand) and revenues generated by increasing inventory levels was important to investors. The more Viread sales that were attributable to inventory stocking, the less the true demand for the drug during the second quarter.

Beginning July 14, 2003, Gilead announced substantially increased second quarter revenues, and identified three primary causes: rising prescription levels for Viread, significant increases in U.S. wholesaler inventories of Viread in advance of an expected price increase on June 27, 2003, and a

favorable foreign currency exchange rate.[2] A Gilead press release on July 31, 2003, reported its final results for the second quarter: net quarterly revenues of $238.9 million, of which $167 million related to Viread. Gilead further announced that it anticipated that third-quarter revenues would be "at or below" those of the second quarter as the wholesalers drew down their excess inventories of Viread.

The July 31 press release also estimated that increasing inventory stocking of Viread accounted for somewhere between $25 million and $30 million of the second quarter revenues. Importantly, the release contained a warning regarding the forward-looking statements therein and specifically warned of Gilead's limited "ability to accurately estimate inventory levels as we must make a great deal of assumptions and must rely on incomplete data to make these estimations." SER 172.[3] Indeed, securities analysts during this period warned that it was difficult to tell how much of the increase was attributable to inventory stocking.

On a publicly accessible July 31 conference call following the press release, petitioner John Milligan, Gilead's Chief Financial Officer, explained to analysts and investors that Gilead expected third-quarter Viread sales to be "at or below" second-quarter sales

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[2] The European currency environment is significant because of the proportion of Viread sales outside the U.S. Gilead reported non-U.S. revenues of $107 million for Viread in the second and third quarters of 2003, compared to $174 million of U.S. sales.

[3] Material not attached to this petition, but included in the petitioners' Supplemental Excerpts of Record in the Ninth Circuit will referred to as SER ___. Material included in respondents' Excerpts of Record in the Ninth Circuit will be referred to as ER ___.

because the second-quarter results reflected wholesalers' decisions to increase their inventories of Viread:

> Of significant note, we believe that a substantial inventory build occurred in U.S. distributor channels during the second quarter as wholesalers anticipated the Viread price increase announced on June 27th. Though difficult to determine the exact figure for this inventory build, we estimate that wholesaler inventories increased by 25 to $30 million during the quarter.

(SER 179, 184)[4]

Gilead's Form 10-Q for the second quarter of 2003 confirmed the previously announced financial results. The Form 10-Q further explained the inventory overstocking: "We estimate that this higher stocking resulted in $25.0 to $30.0 million of additional sales during the second quarter, which may adversely impact sales in the third quarter as wholesalers return to more normal inventory levels and buying patterns." SER 167.

*Third Quarter 2003:* On October 28, 2003, Gilead announced that, as anticipated, its third-quarter Viread revenues had declined, but that both new and total prescriptions for the drug in the U.S. and Europe had increased. Gilead also disclosed that, based on newly available data, it now believed that

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[4] During the call, Dr. Milligan also stated that Gilead expected total revenue in 2003 from Viread sales to be between $550 and $600 million (up from the earlier estimate of $475-500 million). Ultimately, in January 2004, the company reported that it had met those projections with year-end reported total Viread revenues of $566 million. Respondents do not challenge the accuracy of Gilead's 2003 total sales figures.

the wholesalers' inventory build in the second quarter had been $33 million to $37 million, rather than the $25 million to $30 million previously estimated. This was perceived by the market as negative news, as it meant that the true demand for Viread (reflecting the number of patients actually using the drug) going into the third quarter had been less than previously believed.

Gilead's stock price fell $7.46 (12.5%) to $52.00 on October 29 from the closing price of $59.46 the previous day on heavy trading volume. The stock recovered nearly half that loss within one day and recovered fully within a month.

### C. Respondents' Various Efforts To State A Securities Fraud Claim.

Just two weeks after the October 28 announcement, on November 10, 2003, the first complaint was filed on behalf of a putative class, alleging, as relevant here, securities fraud in violation of section 10(b) of the Securities Exchange Act of 1934 and Rule 10b-5. 15 U.S.C. § 78j(b); 17 C.F.R. § 240.10b-5. Respondents seek damages on behalf of all purchasers of Gilead stock from July 14, 2003 through October 28, 2003 based on the October 29 stock drop.

1. The original complaints filed in this action alleged only that petitioners intentionally underestimated the level at which wholesalers had stocked Viread in the second quarter of 2003. That is why the claimed class period begins July 14, 2003 (the date that Gilead originally estimated the second-quarter inventory build) and ends October 28, 2003 (the date Gilead revised that estimate upward). From the point of view of an explanation for the (short-term) drop in Gilead's stock price following the October 28 report, this theory made sense. That is precisely how

analysts at the time explained the disappointing October 28 news.

But the district court concluded that such a theory was not actionable. Respondents had not "allege[d] any facts inconsistent with the conclusion that Gilead's 2003 second quarter financial reports were made in good faith and based on the best information available at the time." Pet. App. 77a. In short, Gilead's estimate of wholesaler inventory over-stocking was wrong, but not fraudulently so. Respondents abandoned this securities fraud theory.

2. Beginning in the Consolidated Amended Complaint, filed April 30, 2004, respondents looked for a different theory to serve as the basis of their effort to recover for Gilead's temporary drop in stock value. For the first time, they alleged that defendants illegally marketed Viread "off-label," i.e., for uses that were not approved by the FDA.

Specifically, they alleged that Gilead had improperly marketed the drug for use by patients who had not yet undergone antiretroviral therapy (treatment-naïve patients) and for use by patients co-infected with HIV/AIDS and Hepatitis B. Relying on two confidential witnesses, respondents claimed that 75-95% of the two witnesses' individual sales resulted from off-label marketing, and that their personal sales data could be extrapolated to all domestic Viread sales.

Respondents also relied upon two letters Gilead received from the FDA. The first, an "Untitled FDA Letter" dated March 14, 2002, alleged that Gilead representatives made misleading oral promotional statements at a December 2001 conference by failing to include risk information when describing the drug's benefits. The second, a "Warning Letter" from

the FDA, dated July 29, 2003, notified Gilead that the FDA considered certain oral representations made by a Gilead representative at a promotional booth during a conference in April 2003 to be improper. The letter stated that the FDA was concerned that the sales representative minimized risk information, failed to disclose that Viread was approved for use only with other antiretroviral agents, and stated that it improved lipid parameters. The fact that the company had received the July 29 letter was publicly disclosed twice: by the FDA on August 7, 2003; and by Gilead, in its Form 10-Q filed with the SEC on August 14, 2003. Respondents have never alleged that the market had any adverse reaction to the disclosure of the FDA Warning Letter. In fact, Gilead's stock price rose following the FDA's public disclosure of the letter and remained unchanged after Gilead's 10-Q filing.

Prior to this Court's ruling in *Dura*, respondents alleged that Gilead's October 28 release had "tacitly admitted that demand for Viread was not as strong as investors were previously led to believe" given the proportion of second-quarter revenues attributable to wholesaler overstocking. Indeed, respondents affirmatively alleged that the purported off-label marketing scheme remained hidden from the market:

> [W]hile disclosing their reliance on wholesaler overstocking, Defendants failed to disclose that the amount of Viread sales and prescriptions was also due to their intentional, improper, and illegal marketing and promotional campaign.

SER 5 ¶ 17, 63 ¶ 18. Neither the Amended Complaint nor its immediate successor attributed the October 29 price decline, directly or indirectly, to any decline in Viread prescriptions in the third quarter of 2003.

Both of those complaints were dismissed, the latter for failure to plead loss causation.

3. It was not until their Fourth Amended Complaint that respondents, for the first time, alleged a theory that sought to connect the October 2003 drop in Gilead's stock price to the allegedly unlawful off-label marketing of Viread and the allegedly fraudulent failure to reveal the extent to which sales of Viread were based on such unlawful conduct.

The first step in respondents' newly minted theory of loss causation asserted a connection between prescriptions written for Viread and the public disclosure of the FDA letter in August 2003. Respondents alleged that the FDA letter "set in motion events that would impede Viread's sales growth and ultimately result in a sharp drop in Gilead's stock price" because it caused physicians to be "less eager" to prescribe Viread, that "[c]ompetitors were able to use the FDA Warning Letter as an argument to physicians to choose their own product over Viread," and that, consequently, prescriptions of Viread materially decreased. ER 35 ¶¶ 14-15, 85 ¶ 200, 86 ¶ 204. As noted above, however, the stock price of Gilead was not adversely affected by the public disclosure of the FDA letter, so respondents had to stretch this putative effect on Gilead's business forward in time to the October 28 earnings report. Respondents asserted that the disclosure of the FDA letter "resulted in sales and prescription[s] for the [third] quarter that did not demonstrate the strong growth that investors had come to expect." ER 86 ¶ 203.

Respondents' loss causation "theory" is really nothing more than speculation about a highly attenuated chain of causation between Gilead's

allegedly improper marketing activities and the drop in Gilead's stock in October 2003. The allegations supporting the theory are devoid of any particularized facts that would support a reasonable, non-speculative belief that respondents could ultimately prove such a theory.

First, respondents offered no basis for inferring that the market understood the disappointing October earnings report to reflect a drop in Viread prescriptions at all, much less a drop attributable to any concerns about unlawful off-label marketing. In fact, respondents do not allege that the company's disclosure, contemporaneous with the earnings report, that Viread prescriptions had actually increased in the third quarter was in any way inaccurate, and there is no allegation in the Fourth Amended Complaint that investors did not believe that disclosure. Respondents have not alleged that any doctors they interviewed ceased or reduced prescriptions of Viread during the third quarter of 2003, let alone in response to the publication of the FDA Warning Letter.

None of the public statements in the record suggests a decline in Viread prescriptions in the third quarter. Gilead's October 28 press release stated that prescriptions continued to grow. A Morgan Stanley analyst report noted that overall Viread sales were down 31% compared to the second quarter, but attributed this to wholesaler inventory stocking, just as respondents had alleged in an earlier version of their complaint. The Morgan Stanley report included a boldfaced front-page headline "**Viread Inventory the Story**," which indicated that *second quarter* "end-user demand run rates were actually lower than previously believed. Thus, while Viread demand continues to grow, it is off a lower base." ER 114-15.

A Bear Stearns analyst report calculated end-user demand rising 17% from the second quarter but similarly downgraded growth projections in light of the inventory stocking misestimation. SER 213. A chart in the Morgan Stanley report shows a consistent trend of upward growth in Viread prescriptions from October 2002-October 2003, accompanied by statistics and charts showing *increasing* prescriptions and market share for Viread. ER 116-18.

Second, and equally important, respondents have never suggested that they can isolate any putative impact of the disclosure of the allegedly unlawful off-label marketing scheme. Gilead, analysts and even the respondents themselves (in all of their earlier complaints) contemporaneously attributed the entire drop in Gilead's stock price on October 29, 2003, to the fact that Gilead was forced to increase its estimate of the degree to which its wholesalers had grown their inventories in the previous quarter and to lower sales in Europe. Respondents do not even attempt to claim that the losses they seek to recover can be segregated from these confounding conditions, conditions to which they had previously attributed the entire stock drop.

**D. The District Court's Dismissal.**

On May 12, 2006, the district court dismissed the Fourth Amended Complaint for failure adequately to plead loss causation under *Dura*. App. 33a-39a. Even applying Rule 8, *id.* at 36a, 39a, the court found:

> Plaintiffs' allegations regarding loss causation are simply too attenuated. . . . [T]hey require the Court to make the unreasonable inference that a public revelation on August 8 *caused* a price drop *three months later* on October 28. . . .

> . . . Even if the FDA Warning Letter caused prac-titioners to reduce their Viread supply, Plaintiffs still fail to connect that with the drop in stock price.

*Id.* at 34a-35a. The district court found no sign that the market was concerned about declining Viread prescription rates:

> [T]he market analyst reports . . . undermine Plaintiffs' theory that the disclosure led to a decrease in demand. The reports do not predict a decrease in demand at all. Indeed, they suggest that the demand for Viread would continue to grow.

*Id.* at 36a. Thus, the district court reiterated its prior conclusion that "'the record reflects that investors never actually learned the extent of Defendants' off-label marketing scheme.'" *Id.* at 35a n. 9.

Finally, the court held that the complaint failed to provide any indication that the plaintiffs could distinguish the loss attributable to the alleged fraud, from loss attributable to other, nonfraudulent factors: "the Court is left to speculate as to what portion, if any, of [the stock drop] should be attributed to the alleged misconduct and what should be attributed to other market factors." *Id.* at 39a.

**E. The Ninth Circuit's Decision.**

The Ninth Circuit reversed. Noting that *Dura* had left open whether Rule 9(b) applies to the loss causation element of securities fraud, the court stated that it did not need to decide whether to apply Rule 8 or Rule 9(b) because under its understanding of even the strict pleading requirements of Rule 9(b), respondents' Fourth Amended Complaint gave "'sufficient detail to give defendants ample notice of

[respondents'] loss causation theory, and to give us some assurance that the theory has a basis in fact.'" App. 14a-15a (quoting *Berson* v. *Applied Signal Tech., Inc.*, 527 F.3d 982, 989-90 (9th Cir. 2008)). Yet, the Ninth Circuit's description of that standard amounted to a substantial weakening of it: "So long as the complaint alleges facts that, if taken as true, plausibly establish loss causation, a Rule 12(b)(6) dismissal is inappropriate." App. 18a.

According to the Ninth Circuit, the October 28 press release could be considered a "corrective disclosure" that caused the public to "finally realize the impact of the off-label marketing and the Warning Letter":

> Our review of the Investors' complaint convinces us that the October drop in stock price was plausibly caused by the Warning Letter.

App. 19a. The Ninth Circuit did not fill in any of the gaps in the attenuated chain of reasoning that led the district court to dismiss the complaint for failure to plead loss causation. The complaint survived, in the Ninth Circuit's view, because the gaps in time and causal connections discussed above do "not render a plaintiff's theory of loss causation per se implausible." *Id.*

## REASONS FOR GRANTING THE PETITION

*Dura* expressly left open the appropriate pleading standard for loss causation because the allegations in *Dura* could be dismissed even "assum[ing], at least for argument's sake, that neither the [Federal] Rules [of Civil Procedure] nor the securities statutes impose any special further requirement in respect to the pleading of proximate causation or economic loss." 544 U.S. at 346. The question whether either the

Federal Rules of Civil Procedure or the securities statutes impose "any special further requirement in respect to pleading" of loss causation now requires this Court's attention in light of the split of authority that has developed. This case provides an excellent vehicle to review the question.

1. There is now a 2-3-1 split of authority regarding the proper pleading standard for loss causation allegations in a securities fraud complaint. Two courts have indicated that Rule 9(b)'s pleading standard applies to loss causation allegations. Three other courts have not expressly concluded that Rule 9(b) applies, but have nonetheless required some form of heightened factual specificity in pleading loss causation. Finally, one court, the Ninth Circuit, follows its own path and holds that factual specificity is not required with regard to loss causation allegations, and that the articulation in a complaint of a not facially implausible *theory* of loss causation will suffice to survive a motion to dismiss.

The Fifth and Seventh Circuits have rigorously applied the Rule 9(b) standard to loss causation. In *Tricontinental*, the Seventh Circuit dismissed a Section 10(b) claim on loss causation grounds, 475 F.3d at 843-44, while allowing a related state-law negligent misrepresentation claim to proceed. The court of appeals acknowledged that both claims required proof of loss causation, but the state-law claim survived because the "negligent misrepresentation claim must be evaluated according to the pleading requirements of Rule 8, not the heightened pleading requirements of Rule 9." *Id.* at 839 n. 10. Similarly, the Fifth Circuit has required loss causation allegations to be pleaded with "particularity," as mandated under Rule 9(b). *Catogas*, 292 F. App'x at 312.

Three other Circuits, the Second, Fourth and Eighth, have not expressly relied upon Rule 9(b), but still have demanded a heightened degree of factual specificity in pleading loss causation. Decisions from both the Second and Fourth Circuits provide strong reasons to apply Rule 9(b)'s particularity requirement to loss causation allegations in a securities fraud case.[5] The Second Circuit has applied Rule 9(b) to loss causation allegations in the RICO context, holding that a plaintiff "must allege loss causation with sufficient particularity such that we can determine whether the factual basis for the claim, if proven, could support an inference of proximate cause." *First Nationwide Bank* v. *Gelt Funding Corp.*, 27 F.3d 763, 770-72 (2d Cir. 1994). Its subsequent Section 10(b) decisions, while not expressly relying on Rule 9(b), have similarly characterized the pleading threshold. See *Lattanzio*, 476 F.3d at 157-58 ("Plaintiffs have not alleged facts to show that Deloitte's misstatements, among others . . . that were much more consequential and numerous, were the proximate cause of plaintiffs' loss; nor have they alleged facts that would allow a factfinder to ascribe some rough proportion of the whole loss to Deloitte's misstatements"); *Lentell* v. *Merrill Lynch & Co.*, 396 F.3d 161, 174-77 (2d Cir. 2005) (complaint must

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[5] The Rule applies, on its face, to all of "the circumstances constituting fraud." The most natural reading of that phrase is that it incorporates all of what *Dura* called the "traditional elements" of fraud at common law, including how the fraud caused the plaintiff harm. *Dura*, 544 U.S. at 343-46. Under the canon of *expresio unius exclusio alterius*, the Rule's exception providing that the element of intent "may be alleged generally" suggests that the drafters of Rule 9(b) intended all the other traditional elements to be pleaded with particularity. *Cf. Leatherman* v. *Tarrant County Narcotics Intelligence & Coordination Unit*, 507 U.S. 163, 168 (1993).

"allege facts to establish that [the defendant's] misstatements . . . concealed the [risk] that materialized and played some part in diminishing the market value of" the company).

The Fourth Circuit has observed that "[a] strong case can be made that because loss causation is among the 'circumstances constituting fraud for which Rule 9(b) demands particularity, loss causation should be pleaded with particularity.'" *Teachers*, 477 F.3d at 185-86. The Fourth Circuit has also indicated that, at a minimum, loss causation "must [be] plead . . . with sufficient specificity to enable the court to evaluate whether the necessary causal link exists." *Id.* at 186. The Eighth Circuit, citing this Court's decision in *Twombly*, has required a plaintiff to allege "sufficient factual information to provide the 'grounds' on which the claim rests." *Schaaf*, 517 F.3d at 549.

The Ninth Circuit, alone among the courts to consider the question, has adopted and applied in this case a pleading standard that demands no factual specificity, but merely the articulation of a theory of loss causation that is not implausible per se. The Ninth Circuit, relying on a decision from the Third Circuit considering loss causation evidence at the summary judgment stage, indicated that "'loss causation becomes most critical at the proof stage.'" App. 17a (citing *McCabe* v. *Ernst & Young, LLP*, 494 F.3d 418, 427 n.4 (3d Cir. 2007)).[6] It ignored *Dura*'s emphasis on the importance of adequate *pleading* of loss causation. *Dura*, 544 U.S. at 347-48. Citing an

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[6] *McCabe* was itself quoting a pre-*Dura* Third Circuit decision. 494 F.3d at 427 n.4. *See EP MedSystems, Inc.* v. *EchoCath, Inc.*, 235 F.3d 865, 884 (3d Cir. 2000). The Third Circuit has not had an opportunity to revisit *EP MedSystems* since *Dura*.

earlier Ninth Circuit ruling, the court below evaluated the complaint only to ensure that it "offers 'sufficient detail to give defendants ample notice of [their] loss causation *theory*, and to give us some assurance that the theory has a basis in fact.'" App. 14a-15a (emphasis added) (quoting *Berson*, 527 F.3d at 989-90). According to the Ninth Circuit, the complaint need only provide enough information to show that the theory of loss causation is "not facially implausible." *Id.* at 17a.

The state of the law is strikingly similar in this context to what it was when the Court granted a writ of certiorari in *Tellabs, Inc.* v. *Makor Issues & Rights, Ltd.*, 127 S. Ct. 2499 (2007), to determine the specificity required to allege the heightened pleading standard for intent under the PSLRA. For the reasons the Court granted certiorari in *Tellabs*, it should grant the petition here.

2. This case provides an excellent vehicle to explore the factual specificity required to plead loss causation adequately in a securities fraud case. The complaint at issue, and found adequate by the Ninth Circuit under its especially lenient standard, implicates both substantive components of *Dura*'s loss causation holding. The Ninth Circuit has required no factual basis to believe that plaintiffs here can prove *either* that the loss occurred after the alleged fraud became generally known to the market, or, even if it had, that plaintiffs have any capacity to isolate the losses attributable to the fraud from other confounding factors.

a. As *Dura* held, "a person who 'misrepresents the financial condition of a corporation in order to sell its stock' becomes liable to a relying purchaser 'for the loss' the purchaser sustains 'when the facts . . . become generally known' and 'as a result' share value

'depreciate[s].'" 544 U.S. at 344 (alteration and omission in original) (quoting *Restatement (Second) of Torts* § 548A, cmt. b, at 107). There is no loss causation where "the purchaser sells the shares quickly *before* the *relevant truth begins to leak out*," because "the misrepresentation will not have led to any loss." *Id.* at 342 (emphasis added). As the Fifth Circuit has read *Dura*, "there is no loss attributable to a misrepresentation unless and until the truth is subsequently revealed and the price of the stock accordingly declines." *United States* v. *Olis*, 429 F.3d 540, 546-48 (5th Cir. 2005).

The Ninth Circuit's "not per se implausible" rule permits a plaintiff to evade entirely pleading any market awareness. The Ninth Circuit's analysis does not require a plaintiff to plead facts showing that the truth *ever* became known to the market. Instead, the rule blesses a complaint that simply asserts that a poor earnings report may have amounted to a disclosure of the consequences of an alleged fraud (here, weakened sales allegedly due to fewer prescriptions) without any factual allegations indicating what the market learned and when and how it understood what it had learned.

When Gilead's stock first dropped, analysts attributed the bad news to the revised estimates of wholesaler inventory stocking, and the initial complaints did the same. Only after their original theory of fraud failed did respondents allege that the October 28 earnings report amounted to a disclosure to the market about the scope of off-label marketing via declining prescriptions. But this characterization of events was nothing more than the lawyers' speculative recharacterization of events. Their new theory of loss causation was unaccompanied by any specific factual allegations that, if proved, would

establish that the market understood the report as the lawyers for respondents now imagine it could have. It is clear that under the standards of other courts, the pleading tactic employed by respondents here would have failed.

The disclosures to the market in *Tricontinental* concerned accounting irregularities in a company's 1998 and 1999 financial statements and the company's subsequent bankruptcy. The plaintiffs complained about the 1997 financial statements, and alleged a facially plausible theory: "the 1997 fraud was part of an on-going scheme to overrepresent revenue and . . . the 1998 audit relied in part on historic information." *Tricontinental*, 475 F.3d at 842. The Seventh Circuit held that *Dura* requires more direct allegations of market awareness of the truth: a plaintiff must "specify" that a loss was caused when the truth "'became generally known,'" and the plaintiff "has not identified any statements by [the company or its auditor] that made 'generally known' any problems or irregularities in the 1997 audited financial statement." *Id.* at 843 (quoting *Dura*, 544 U.S. at 344, 345).

The Fifth Circuit, in *Catogas*, rejected a chain of causation by which a stock drop on the news that a company faced potential delisting of its stock was connected to misrepresentations about its stock option accounting. The plaintiffs argued that an internal investigation into the accounting had caused the company to file its annual report late, which had exposed it to delisting. *Catogas*, 292 F. App'x at 314-15. The Fifth Circuit read *Dura* to require that "[p]laintiffs must allege . . . that the market reacted negatively to a corrective disclosure, which revealed the falsity of [the defendant's] previous representations." *Id.* at 314. The claim in *Catogas* failed because

"the only information . . . *not* previously disclosed to the market—*potential delistment*—did nothing to reveal previous misstatements with respect to [the company's] stock-option accounting." *Id.* at 315.

The Fourth Circuit, in *Teachers*, even though not applying Rule 9(b) standards, dismissed a pleading under its (and the Second Circuit's) heightened Rule 8 standard—loss causation must be pled "with sufficient specificity to enable the court to evaluate whether the necessary causal link exists"—that likewise cannot be squared with the permissive approach to pleading taken by the Ninth Circuit. In *Teachers*, the complaint premised loss causation on the theory that an executive's lawsuit alleging ongoing schemes to inflate revenue revealed the fraudulent nature of the company's prior accounting. *Teachers*, 477 F.3d at 186-87. The court rejected the plaintiffs' invitation to speculate about the plausible causes of the market's negative reaction to the lawsuit:

> While plaintiffs respond that "the market *would have construed* [the executive's] allegations . . . broadly since [the company] had previously denied that it engaged in round-tripping," the problem remains that [the executive's] 2003 complaint is devoid of even general allegations of round-tripping.
>
> . . . .
>
> To allege loss causation in this case, plaintiffs would have to allege that the market reacted to new facts disclosed [on the date of the lawsuit] that revealed [the company's] previous representations to have been fraudulent.

*Id.* at 187 (emphasis added).

Other cases have likewise required a factual basis to believe that the market understood an alleged disclosure to reveal what securities fraud plaintiffs assert it revealed. See also *Joffee* v. *Lehman Bros.*, 209 F. App'x 80, 81 (2d Cir. 2006); *Glaser* v. *Enzo Biochem, Inc.*, 464 F.3d 474, 479 (4th Cir. 2006), *cert. denied*, 549 U.S. 1304 (2007); *DE&J Ltd. P'ship* v. *Conaway*, 133 F. App'x 994, 995, 999-1000 (6th Cir. 2005). Without such a factual basis, a securities fraud complaint should be dismissed, according to these decisions. Yet the Ninth Circuit permits a complaint devoid of such factual allegations to survive. The Ninth Circuit's unique leniency, especially in light of the dispute among the circuits regarding whether Rule 9(b) applies, warrants this Court's review.

b. The second part of *Dura*'s loss causation test is even more problematic for respondents and the Ninth Circuit. *Dura* requires respondents to allege facts which provide more than a speculative reason to believe they can isolate the effects of the fraud from other causes of their loss. They have not even tried to do this, and the Ninth Circuit freed them from that obligation. No other court that has considered the question would allow such a complaint to survive a motion to dismiss.

The potentially confounding causes of the stock price drop in October 2003 are obvious. Analyst reports, statements from Gilead officers, and the plaintiffs themselves all attributed the disappointing earnings report to a greater than anticipated wholesaler inventory build in the second quarter and corresponding drawdown in the third quarter. Even if it were true that there had been some decline in Viread demand, and even if it were true that the drop had been caused by disclosure of the FDA Warning Letter, the effects of wholesaler inventory build and

subsequent drawdown did not simply disappear. Yet the Ninth Circuit did not require that respondents allege any facts that suggest they can isolate the effects of the alleged fraud from the myriad other factors *known* to have impacted the stock price in October 2003.[7] Other courts, applying an appropriately more stringent pleading standard, require more.

The Second Circuit, in *Lattanzio*, held that loss causation was not adequately pleaded against auditors of a company that went bankrupt, where the auditors signed off on financial statements that overstated shareholder equity by 65% due in part to a $97 million understatement of liabilities. *Lattanzio*, 476 F.3d at 151-53. The plaintiffs argued that their losses were caused by the company's unexpectedly bad financial condition, but the Second Circuit rejected the claim on the pleadings. The Second Circuit held that the losses plaintiffs sought could not all be attributable to auditors' alleged misstatements, and that the complaint was properly dismissed because the plaintiffs had not "alleged facts that would allow a factfinder to ascribe some rough

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[7] There is good reason, even at this early stage of the litigation, to believe that the impact of factors unrelated to the alleged fraud is substantial. The allegations of fraud went to a systemic weakness in the market of Gilead's then-leading product. If that were the principal or even a substantial reason for the drop in the stock price, the price would not recover quickly. Yet publicly available sources that are appropriate to consider on a motion to dismiss reveal plainly that within a month, the entire loss had been recovered, and that Gilead actually reached its originally projected total Viread sales for 2003. The Ninth Circuit simply ignored these facts.

proportion of the whole loss to [the auditor's] misstatements." *Id.* at 158.[8]

In *Schaaf*, the plaintiff bondholders sued two lenders who allegedly concealed defaults in "debt-to-worth" loan covenants by the issuing company (United). The lenders eventually declared defaults and stopped lending to United, causing loss to United's bondholders. In the case of one lender (RFC), the plaintiffs alleged that it stopped lending after sending notice that United violated those very same debt-to-worth covenants. But given the passage of months between the notice and RFC's refusal to lend, the Eighth Circuit held that "plaintiffs have not adequately alleged how RFC's 1998 letter, or the breach it recognized, *caused* RFC to stop lending money to United." *Schaaf*, 517 F.3d at 552-53. As the Eighth Circuit observed,

> [t]he passage of time in this case is particularly significant, because the complaint alleges that United suffered from poor home sales in the fall of 1998, which caused slowdowns in production and closings, which in turn reduced the availability of cash to United. The *Dura* court noted that such a change in economic circumstances could defeat a plaintiff's attempt to prove loss causation and give added significance to the passage of time.

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[8] *See also ATSI Commc'ns, Inc.* v. *Shaar Fund, Ltd.*, 493 F.3d 87, 106-07 (2d Cir. 2007); *Leykin* v. *AT&T Corp.*, 216 F. App'x 14, 16 (2d Cir. 2007), *aff'g* 423 F. Supp. 2d 229, 246 (S.D.N.Y. 2006). Here the risk of wholesaler inventory stocking was always a fully-disclosed risk. And, as of the date of the disclosure of the FDA Warning Letter, so was off-label marketing. Thus, under the Second Circuit's *Lattanzio* standard, neither risk was "concealed" by Gilead prior to the October 28 press release.

*Id.* at 553. In at least the Second and Eighth Circuits, the failure of the complaint to account for known confounding factors running through an attenuated chain of alleged causation is fatal; in the Ninth Circuit it is not even a wound.

The Ninth Circuit's "not per se implausible" pleading standard permits plaintiffs to substitute a chain of speculative hypotheses for facts that give reason to believe plaintiffs can actually prove loss causation under *Dura*. This Court in recent years has frequently dismissed pleadings that rested on overly attenuated chains of causation. See *Stoneridge Inv. Partners, LLC* v. *Scientific-Atlanta, Inc.*, 128 S. Ct. 761, 769-70 (2008); *Anza* v. *Ideal Steel Supply Corp.*, 547 U.S. 451, 458-60 (2006); *Holmes* v. *SIPC*, 503 U.S. 258, 269-74 (1992). The Ninth Circuit's not "per se implausible" standard for pleading loss causation opens the door to precisely the kinds of "intricate, uncertain inquiries" this Court warned against in *Anza*. 547 U.S. at 459-60. Accordingly, this case provides an excellent opportunity for this Court to articulate a pleading standard for loss causation that comports with the Court's recent pleading and securities law cases.

c. The Ninth Circuit stated that it did not need to decide whether to apply Rule 9(b). App. 14a. The fact that the Ninth Circuit believed its analysis was consistent with Rule 9(b) standards provides still further reason for this Court to review this decision.

The Ninth Circuit's "not per se implausible" standard is wholly irreconcilable with Rule 9(b), which requires pleading of "the who, what, when, where, and how: the first paragraph of any newspaper story." *DiLeo* v. *Ernst & Young*, 901 F.2d 624, 627 (7th Cir. 1990) (Easterbrook, J.); see also *Lachmund* v. *ADM Investor Servs., Inc.*, 191 F.3d

777, 784 (7th Cir. 1999) (pleading of misrepresentations under Rule 9(b) "must be specific with respect to the time, place, and content of the alleged false representations, the method by which the misrepresentations were communicated, and the identities of the parties to those misrepresentations"). Under Rule 9(b), "a plaintiff claiming fraud or mistake must do more pre-complaint investigation to assure that the claim is responsible and supported, rather than defamatory and extortionate." *Borsellino* v. *Goldman Sachs Group, Inc.*, 477 F.3d 502, 507 (7th Cir. 2007) (quotation and alteration omitted). A plaintiff "cannot sufficiently plead fraud by simply providing a method for the defendant to discover the underlying details. If [the plaintiff] has access to the details necessary to make these allegations, it must plead them and not just tell the defendants to go find them." *See ATSI Commc'ns, Inc.* v. *Shaar Fund, Ltd.*, 493 F.3d 87, 106-07 (2d Cir. 2007).

"Rule 9(b) has four purposes: First, the rule ensures that the defendant has sufficient information to formulate a defense by putting it on notice of the conduct complained of . . . . Second, Rule 9(b) exists to protect defendants from frivolous suits. A third reason for the rule is to eliminate fraud actions in which all the facts are learned after discovery. Finally, Rule 9(b) protects defendants from harm to their goodwill and reputation." *United States ex rel. Harrison* v. *Westinghouse Savannah River Co.*, 352 F.3d 908, 921 (4th Cir. 2003) (internal quotations omitted). The Ninth Circuit's "not per se implausible" standard only addresses the first of these purposes, which is what Rule 8 historically achieved, and completely disregards the rest.

The discovery that would be required to establish respondents' theory of causation in this case serves to

illustrate why Rule 9(b) should apply with particular force to theories of proximate causation that do not rest on the market directly learning the circumstances constituting the fraud. A typical "corrective disclosure" case is premised upon information that is, by definition, *public knowledge* at the time a complaint is filed. Thus, as *Dura* anticipated, it will "not prove burdensome for a plaintiff who has suffered an economic loss to provide a defendant with some indication of the loss and the causal connection that the plaintiff has in mind." *Dura*, 544 U.S. at 347.

Here, by contrast, respondents admit they will need to conduct discovery of Gilead's internal sales records to seek to substantiate their allegations. Respondents will also need extensive discovery of third-party wholesalers and doctors to fish for support for their theory that the independent actions of those parties were caused by the FDA Warning Letter rather than some other cause, support that is thus far absent from their pleadings. Not only will this be expensive and burdensome discovery in pursuit of facts that there is no basis in the complaint to believe respondents can or will uncover, but it will place the incendiary charge of fraud before Gilead's customers, thus inflicting the kind of reputational damage against which Rule 9(b) protects.

The shifting theories of fraud and loss causation that respondents have pled throughout this litigation reflect the opposite of what Rule 9(b) is supposed to ensure. Respondents asserted fraud quickly (about two weeks after the October 28 report and market response thereto) and have been developing theories to support their rash assertion ever since. Rule 9(b) is supposed to ensure that *prior* to filing a complaint, the plaintiff has done sufficient factual digging to warrant a public attack on the defendant's reputation

and imposing on the defendant the cost of defending the serious charge being asserted. The Ninth Circuit's casual dismissal of the meaningful pleading burdens of Rule 9(b) make this an especially appropriate case in which to determine whether Rule 9(b) or some other form of heightened pleading applies here.

Further, the theory of loss causation upon which respondents settled reflects a particularly pernicious sort of backward-looking, sue-first-develop-a-story-later approach. Respondents initially ignored the FDA Warning Letter, which was perfectly sensible because analysts and investors did too. There was and is no reason to believe the market was concerned about the Warning Letter's effect on demand for Viread or Gilead's business in general. Only after their initial effort to plead a claim failed did they seize upon the Warning Letter as a causal hook. If courts are to permit such regulatory notices to serve as the after-the-fact hooks upon which plaintiffs can, on the basis of no facts, hang their theory of loss causation and force a company to endure lengthy and costly securities fraud litigation, then regulated industries—including drug companies, insurance companies, power companies, banks, and many others—will find themselves especially exposed to suits whenever a stock drop occurs within some undefined period of months after a regulatory notice is issued. This Court has made clear that the securities laws do not permit such costs to be so readily imposed on regulated entities.

3. The pleading standard for loss causation is an important issue for this Court to resolve. Securities litigation has remained active and will likely only gain further steam in the face of a highly volatile

market.[9] This Court has repeatedly noted that Congress passed the PSLRA "to curb frivolous, lawyer-driven litigation" resulting in "'nuisance filings, targeting of deep-pocket defendants, vexatious discovery requests and manipulation by class-action lawyers.'" *Tellabs*, 127 S. Ct. at 2508-09 (quoting *Merrill Lynch, Pierce, Fenner & Smith Inc.* v. *Dabit*, 547 U.S. 71, 81 (2006)). In the PSLRA, Congress armed courts with the tools necessary to end speculative securities litigation at an early stage, before it could cause harm to a publicly traded company and our financial markets in general. See *Id.* at 2508 ("Setting a uniform pleading standard for § 10(b) actions was among Congress' objectives when it enacted the PSLRA."). Loss causation is often a contested and potentially dispositive element of a securities fraud claim. If an unduly lenient pleading standard applies to loss causation allegations, as the Ninth Circuit held here, then much of the good Congress sought to accomplish with the PSLRA will be lost. Given the ability of plaintiffs' lawyers to find

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[9] One 2006 study found that the average U.S. listed company stands a 10% chance of facing a securities class action in any given five-year period. *See Interim Report of the Committee on Capital Markets Regulation* 74 (Nov. 30, 2006), *available at* http://www.capmktsreg.org/pdfs/11.30Committee_Interim_ReportREV2.pdf. And the incidence of such suits is rising: 217 federal securities class actions were filed from July 2007 through June 2008, a 72% increase over the levels from 2005-07. *See* Cornerstone Research, *Securities Class Action Filings, 2008 Mid-Year Assessment* 2 (2008), *available at* http://securities.cornerstone.com/pdfs/2008%20Mid-Year%20Assessment.pdf. Indeed, 9.2% of the companies in the S&P 500 index, accounting for 17% of the market value of that index, were named as defendants in securities class actions filed in 2008 alone. *See* Cornerstone Research, *Securities Class Action Filings, 2008: A Year in Review* 7 (2008), *available at* http://securities.cornerstone.com/pdfs/YIR2008.pdf.

putative plaintiffs anywhere in the United States, the existence of a single outlying Circuit promises to promote forum shopping and expose corporations that sell securities in national markets to the burdens of litigation that would not exist in any other Circuit. Only this Court can remedy that problem.

## CONCLUSION

For the foregoing reasons, the petition for writ of certiorari should be granted.

Respectfully submitted,

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February 6, 2009

# APPENDIX

# APPENDIX A

## UNITED STATES COURT OF APPEALS
## NINTH CIRCUIT

No. 06-16185

In re GILEAD SCIENCES SECURITIES LITIGATION.

RICK HARTMAN, on behalf of himself and all others similarly situated; TRENT ST. CLARE; TERRY JOHNSON,
*Plaintiffs-Appellants,*

v.

GILEAD SCIENCES, INC.; JOHN C. MARTIN; JOHN F. MILLIGAN; MARK L. PERRY; NORBERT W. BISCHOFBERGER; ANTHONY CARRACIOLO; WILLIAM LEE,
*Defendants-Appellees.*

Argued and Submitted Dec. 6, 2007
Filed Aug. 11, 2008

Appeal from the United States District Court
for the Northern District of California;
Martin J. Jenkins, District Judge, Presiding.
D.C. No. CV-03-04999-MJJ.

Before: ALEX KOZINSKI, *Chief Judge*, HAWKINS, and ROBERT E. COWEN,* *Circuit Judges*.

MICHAEL DALY HAWKINS, *Circuit Judge*:

A group of individual investors brought this securities fraud action on behalf of themselves and

* The Honorable Robert E. Cowen, Senior United States Circuit Judge for the Third Circuit, sitting by designation.

a proposed class comprising all individuals (collectively, the "Investors") who purchased Gilead Sciences, Inc.'s ("Gilead") publicly traded securities between July 14, 2003, and October 28, 2003 ("class period"). They allege that Gilead misled the investing public by representing that demand for its most popular product was strong without disclosing that unlawful marketing was the cause of that strength.

The district court dismissed under Rule 12(b)(6) of Civil Procedure, holding that the Investors failed to sufficiently allege loss causation. We have jurisdiction under 28 U.S.C. § 1291, and we reverse.

## *FACTS AND PROCEDURAL HISTORY*

### *I. The Complaint's Allegations*

The Investors' Fourth Amended Complaint ("complaint") alleges violations of sections 10(b) and 20(a) of the Securities Exchange Act of 1934, 15 U.S.C. §§ 78j(b), 78t(a), and SEC Rule 10b-5, 17 C.F.R. § 240.10b-5. The complaint names as defendants Gilead and some of its top officers ("Officers").

Taking its allegations as true, the complaint tells the following story about Gilead and its marketing practices.[1]

Gilead is a biopharmaceutical company that specializes in developing and marketing treatments for life-threatening diseases. One of the company's

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[1] We recount only those facts necessary for understanding the loss causation issue. The complaint, which spans over seventy pages, offers much greater detail. Because we disagree with the district court on the issue, we frequently quote the complaint to demonstrate that the Investors did in fact explicate the causal logic underlying their theory.

commercial products is Viread, an antiretroviral agent used in combination with other drugs to treat HIV.

Gilead's fortunes, as reflected in its stock price, depended heavily on Viread's commercial success. Sales of Viread amounted to about 65% of Gilead's total revenues at all relevant times of this action. "Wall Street analysts looked to sales of Viread, Gilead's most important and most promoted drug, to gauge whether the Company's business was on track and growing. If Gilead failed to publicly report healthy, growing Viread sales, its stock price would be greatly diminished."

Although Gilead had a clear incentive to aggressively promote Viread, it was required to comply with federal law, including the Food and Drug Administration's ("FDA") marketing regulations. Generally, those regulations prohibit the marketing of drugs for non-FDA-approved uses, commonly referred to as "off-label" uses. "For example, it would be considered off-label for a company to market a FDA-approved HIV/AIDS drug as also being effective for fighting Hepatitis B infection . . . if such use of the drug had not been reviewed and approved by the FDA and included in the" drug's FDA-approved package labeling. While physicians are free to prescribe drugs for off-label uses,[2] they rely on the FDA-approved prescribing information to determine which drugs can be used safely and

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[2] *See* 21 U.S.C. § 396; *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350-51 & n. 5, 121 S.Ct. 1012, 148 L.Ed.2d 854 (2001) (explaining that "the FDA is charged with the difficult task of regulating the marketing and distribution of medical devices without intruding upon decisions statutorily committed to the discretion of health care professionals").

effectively by patients with specific health problems. The FDA approved Viread for use in approximately 40% of the available HIV patient pool. Repeatedly violating the FDA's off-label marketing regulations in an effort to have Viread prescribed to some of the remaining 60% of available HIV patients, Gilead and its officers:

> implemented a scheme to promote and market Viread with off-label, false, and misleading statements in violation of the Federal Food, Drug, and Cosmetic Act. In order to gain market share, artificially increase perceived demand, and increase sales, Gilead officers, executives, and clinical personnel, with the express knowledge and approval of the [Officers], routinely and consistently provided Gilead's sales and marketing team with off-label information and encouraged, expected, and directed them to use it to sell Viread. . . .

Gilead's management began preparing Gilead's sales staff for off-label marketing as early as September 2001, one month before Viread received FDA approval. Management continued to encourage off-label marketing throughout 2002 and the first half of 2003.

These training efforts produced their intended effect. According to two confidential witnesses who served as Gilead salespeople,[3] Viread "off-label marketing took three forms: (1) marketing to HIV

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[3] One of the confidential witnesses served as "a member of Gilead's Field Marketing Advisory Committee, a select committee of Gilead sales and marketing staff that periodically met to discuss theories and strategies for marketing and selling Viread."

patients co-infected with Hepatitis B; (2) marketing Viread as a first-line or initial therapy for HIV infection; and (3) marketing against Viread's safety profile." Ultimately, 75% to 95% of Viread sales resulted from off-label marketing efforts.

The company and its Officers emphasized to the public that they carefully complied with federal and state regulations, when in fact they knew that they were acting unlawfully by aggressively marketing Viread for off-label uses.

The first sign of trouble came on March 14, 2002, when the FDA sent an "Untitled Letter" to Gilead that accused the company of understating the risks of Viread—a form of improper off-label marketing. The letter ordered Gilead to "immediately cease" this practice. On March 21, 2002, per the FDA's request, Gilead sent a reply that acknowledged receipt of the FDA's letter and agreed to immediately stop off-label marketing. This was not done. In fact, Gilead's off-label marketing increased, either at the Officers' direction or with their knowledge and tacit encouragement.

By June 2003, Gilead's off-label marketing put it in the position to raise Viread's price. Consistent with standard industry practice, Gilead informed national drug wholesalers of this plan in advance of the price increase. The wholesalers (there are the three major ones that purchase approximately ninety percent of drug manufacturers' drugs) typically stockpile drugs in advance of price increases so that they can resell at a higher price to retailers after the increase takes effect.

Because Gilead had "illegally inflated sales and artificially inflated demand for Viread, the major

drug wholesalers stockpiled mass quantities of Viread in advance of the June 2003 price increase. This wholesaler stockpiling would not have occurred but for the off-label marketing and the resulting creation of an artificially increased demand for Viread." The stockpiling furthered Gilead's fraudulent scheme by confirming "the impression that Viread was in high demand and that Gilead's financial and operational results were strong."

On July 14, 2003, Gilead issued a press release announcing that it anticipated its second quarter financial results would exceed analysts' expectations, and explaining that the company's success "was driven primarily by strong sales growth of Viread. . . . Increasing Viread sales reflect broader prescribing patterns in all commercial markets, as well as increases in U.S. wholesaler inventory levels in the second quarter in anticipation of a Viread price increase."

These statements were materially false and misleading because Gilead and its Officers' "marketing and promotional activities for Viread were not in compliance with FDA approved guidelines, violated federal laws, and created serious public health and safety implications for Viread users." Gilead's promotional scheme was designed to, and did, create the impression that demand for Viread was strong. This campaign was misleading, however, because it was unlawful off-label marketing that was driving prescription volume[4]—and Gilead had already been ordered to cease such marketing.

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[4] The Investors concluded that between $86.7 million and $109.82 million of Viread's $115.6 million in domestic sales during the second quarter of 2003 could be attributed to off-label marketing.

While securities analysts, for the most part, reacted favorably to the July 14, 2003, press release, Gilead and its Officers felt the need to respond to some analysts' concern that second quarter revenues were primarily attributable to the wholesaler stockpiling, and not a result of strong demand. On the same day that the press release was issued, a Gilead spokeswoman, acting with the knowledge and approval of Gilead and its officers, told Bloomberg News that "[t]he main reason for the jump in Viread sales is an increase in prescriptions, not inventory stocking." This statement was misleading. It created the impression that demand for Viread was strong, which it was, but for reasons that were not well-understood by the public. Omitting the role of off-label marketing in a press release highlighting the drug's success made a true statement (that demand was strong) also a misleading one.

Gilead's financial news had a marked effect on its stock price. On July 14, the price of Gilead shares closed at $67.25, up $7.97 from the previous day's closing price of $59.28 per share. This 13.4% increase represented a near-record high.

Some two weeks later, the FDA issued a July 29 Warning Letter[5] that chastised Gilead for statements made by one of its sales representatives at

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[5] The Complaint explains:

> According to the FDA's website and the FDA's Regulatory Procedures Manual, warning letters such as this are written communications from the [FDA] to a company notifying the company that the [FDA] considers one or more promotional pieces or practices to be illegal. . . . A warning letter is much more serious than an untitled letter.

the 15th National HIV/AIDS Update Conference in March and April of 2003. The letter stated that the employee "made oral statements that minimized the risk information and broadened the indication for Viread." It reminded Gilead of the Untitled Letter, expressed the "significant public health and safety concerns raised by these repetitive promotional activities," and ordered Gilead to make corrective disclosure. Gilead made such disclosure to the conference attendees on November 7, 2003.

On August 7, 2003, the FDA made public its Warning Letter. Gilead's shareholders and the investing public did not find it very significant, though, because they failed to appreciate the extent of Gilead's off-label marketing, and thus could not foresee the letter's impact on Viread's sales.

The public's underestimation of Viread's troubles was reflected in Gilead's share price. Notwithstanding the public revelation of the letter, shares closed at higher prices than they opened on both August 7 and August 8. Indeed, by the end of August, the stock was trading a few dollars higher than it had been at the beginning of the month, without having experienced any significant fluctuations.

Yet, "[u]nbeknownst to investors, the disclosure of the FDA Warning Letter had a detrimental effect on Viread sales. Physicians, now alerted to Gilead's illegal marketing efforts and to the safety problems with Viread, were less eager to prescribe it to their patients." Competitors invoked the letter in efforts to persuade physicians to switch from Viread to their products. In the remaining weeks of August, there was a "marked drop in prescriptions and sales" of Viread. Although the Investors lack precise sales figures, a Morgan Stanley analyst report

shows that Viread prescriptions experienced a "sharp drop" in August 2003, followed by "flattened growth" for the remainder of the third quarter. The prescriptions would have suffered further decline were it not for certain side-effects that made it dangerous for some patients to discontinue using the drug.

The wholesalers observed the initial drop in sales and prescriptions of Viread, and the ensuing slow growth. Because Viread was underperforming relative to the expectations generated by the second quarter reports, the wholesalers drew down much more of their excess inventory than they had originally planned, letting supply of Viread drop to the lowest level in four quarters, and well below the industry average for other drugs.

Although wholesalers recognized Viread's struggles, the public continued to misunderstand the significance of the Warning Letter. Gilead did nothing to correct that misunderstanding. In its Form 10-Q reporting on the 2003 second quarter, issued on August 14, Gilead persisted in emphasizing the increased volume of Viread's second quarter sales without discussing the role of off-label marketing. Although the Form 10-Q did briefly address the Warning Letter, it failed to reveal the activities that gave rise to that letter, or the impact the letter would have on sales of Viread.

The Officers exploited the public's ignorance. In the days between the receipt and public disclosure of the Warning Letter, two of the Officers each sold over $3 million worth of stock. On August 7, the day the FDA disclosed the letter, Gilead's Senior Vice President/Chief Financial Officer sold nearly $700,000 worth of shares. Throughout August,

while the market misapprehended Gilead's impending troubles, the Officers continued to sell off substantial numbers of shares. This activity was "unusual and suspicious" because this was the first month in which all of the Officers sold stock. More to the point, this was proof that the Officers acted with knowledge or with deliberate recklessness when they issued materially false and misleading documents and statements that were disseminated to the investing public.

Not until October 28, 2003, did the public finally realize the impact of the off-label marketing and the Warning Letter. After the markets closed that day, Gilead issued a press release detailing third quarter financial results. The public learned that Viread sales fell significantly below expectations because there had been substantially more overstocking by wholesalers than previously reported. Accordingly, third quarter prescriptions were filled by wholesalers' existing inventory, and wholesalers did not reorder Viread at a commensurate level. Market analysts attributed the disappointing sales to "lower end-user demand." That lower end-user demand, as noted, was a direct result of the Warning Letter, which had exposed Gilead's unlawful off-label marketing efforts to physicians.

The market was "stunned" by the third quarter results. Share prices closed at $59.46 on October 28, before the press release was circulated. It may be the case that the market had already begun to slowly incorporate the information regarding Viread's off-label marketing into the share price. But the third-quarter earnings release made the effect of that information inescapably clear. The day after the press release was issued, trading volume

of Gilead shares was up 1,400% from its average daily level. The day opened with Gilead's price per share at $50.69, and closed with a price of $52 per share, a 12% decrease from the previous day's closing price.

Summing it all up,

> At all relevant times, the material misrepresentations . . . directly or proximately caused or were a substantial contributing cause of the damages sustained by [the Investors]. . . . [Gilead and the Officers] made or caused to be made a series of materially false or misleading statements about Gilead's sales, business, product marketing and promotion, prospects, operations and financial results. These material misstatements had the cause and effect of creating in the market an unrealistically positive assessment of Gilead . . . thus causing the Company's publicly traded securities to be overvalued and artificially inflated at all relevant times.

*II. The District Court's Decision*

The district court dismissed the complaint with prejudice. Based on the Investors' allegations and judicially-noticed documents that had been referenced in the complaint, the court concluded that the Investors had failed to adequately plead loss causation as that requirement was articulated in *Dura Pharmaceuticals, Inc. v. Broudo*, 544 U.S. 336, 125 S.Ct. 1627, 161 L.Ed.2d 577 (2005).

Specifically, the district court found the complaint failed to

> connect the following chain of events . . . : 1) that [Gilead's and the Officers'] alleged failure

> to disclose the off-label marketing scheme caused a material increase in sales; 2) that practitioners materially decreased their demand for Viread due to the publication of the FDA Warning Letter; and most importantly, 3) that the alleged decrease in sales due to the FDA letter proximately caused Gilead's stock to decrease three months later[.]

The district court rested its decision exclusively on loss causation, and did not consider whether the Investors sufficiently alleged falsity or scienter.

## *DISCUSSION*

### *I. Standards of Review*

"We review de novo the district court's dismissal of a complaint for failure to state a claim under Federal Rule of Civil Procedure 12(b)(6). On review, we accept the plaintiffs' allegations as true and construe them in the light most favorable to plaintiffs." *Gompper v. VISX, Inc.*, 298 F.3d 893, 895 (9th Cir.2002) (citation omitted). "The court need not, however, accept as true allegations that contradict matters properly subject to judicial notice or by exhibit. Nor is the court required to accept as true allegations that are merely conclusory, unwarranted deductions of fact, or unreasonable inferences." *Sprewell v. Golden State Warriors*, 266 F.3d 979, 988 (9th Cir.2001) (citation omitted), *amended on other grounds*, 275 F.3d 1187 (9th Cir.2001). The complaint is properly dismissed if it fails to "plead 'enough facts to state a claim to relief that is plausible on its face.'" *Weber v. Dep't of Veterans Affairs*, 521 F.3d 1061, 1065 (9th Cir.2008) (quoting *Bell Atl. Corp. v. Twombly*, --- U.S. ----, 127 S.Ct. 1955, 1974, 167 L.Ed.2d 929 (2007)).

*II. Applicable law*

Section 10(b) of the Securities Exchange Act of 1934 makes it unlawful "[t]o use or employ, in connection with the purchase or sale of any security . . . any manipulative or deceptive device or contrivance in contravention of such rules and regulations as the Commission may prescribe." 15 U.S.C. § 78j(b). Pursuant to this section, the Securities and Exchange Commission promulgated Rule 10b-5, which makes it unlawful:

> (a) To employ any device, scheme, or artifice to defraud,
>
> (b) To make any untrue statement of a material fact or to omit to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading, or
>
> (c) To engage in any act, practice, or course of business which operates or would operate as a fraud or deceit upon any person, in connection with the purchase or sale of any security.

17 C.F.R. § 240.10b-5.

We have identified five basic elements of a Rule 10b-5 claim: "(1) a material misrepresentation or omission of fact, (2) scienter, (3) a connection with the purchase or sale of a security, (4) transaction and loss causation, and (5) economic loss." *In re Daou Sys., Inc.*, 411 F.3d 1006, 1014 (9th Cir.2005) (citing *Dura Pharms.*, 544 U.S. at 341-42, 125 S.Ct. 1627).

Because the district court addressed only loss causation under Rule 10b-5, we will limit our consideration to that issue, "following the general

rule [that] a federal appellate court does not consider an issue not passed upon below." *Miller v. Thane Int'l, Inc.*, 519 F.3d 879, 892 (9th Cir.2008) (alteration in original; internal quotation marks omitted). A plaintiff bears the burden of proving that a defendant's alleged unlawful act "caused the loss for which the plaintiff seeks to recover damages." 15 U.S.C. § 78u-4(b)(4). To establish loss causation, "the plaintiff must demonstrate a causal connection between the deceptive acts that form the basis for the claim of securities fraud and the injury suffered by the plaintiff." *Daou*, 411 F.3d at 1025. The misrepresentation need not be the sole reason for the decline in value of the securities, but it must be a "'substantial cause.'" *Id.* (quoting *Robbins v. Koger Props., Inc.*, 116 F.3d 1441, 1447 n. 5 (11th Cir.1997)).

Rule 9(b) of Civil Procedure provides: "In alleging fraud . . . a party must state with particularity the circumstances constituting fraud. . . ." Gilead and the Officers contend that the Investors' loss causation arguments should be subject to this heightened pleading requirement, although they recognize that the Supreme Court has not decided the issue. *See Dura Pharms.*, 544 U.S. at 346, 125 S.Ct. 1627. The Investors argue that Rule 8(a)(2)'s "short and plain statement" requirement should control loss causation pleading.

We need not resolve this issue today. Rule 9(b) imposes the heightened requirement so that the fraud-action defendant "can prepare an adequate answer from the allegations." *Odom v. Microsoft Corp.*, 486 F.3d 541, 553 (9th Cir.2007) (internal quotation marks omitted). As we explain below, the Investors' complaint offers "sufficient detail to give

defendants ample notice of [their] loss causation theory, and to give us some assurance that the theory has a basis in fact." *Berson v. Applied Signal Tech., Inc.*, 527 F.3d 982, 989-90 (9th Cir. 2008). Therefore, under either Rule 8 or Rule 9, the Investors have sufficiently pleaded loss causation.

*III. The Sufficiency of the Complaint*

The district court identified *Dura Pharmaceuticals* as the authority that doomed the Investors' complaint. *Dura* featured plaintiffs who alleged that they "paid artificially inflated prices" for Dura's securities and "suffered damages thereby." *Dura*, 544 U.S. at 339-40, 125 S.Ct. 1627 (alterations, emphasis, and quotation marks omitted). The court below had held that loss causation was established merely by demonstrating that share prices on the date of purchase were inflated. *Broudo v. Dura Pharms., Inc.*, 339 F.3d 933, 938 (9th Cir.2003).

The Supreme Court reversed, and held that an inflated purchase price alone is not enough to establish loss causation. *Dura*, 544 U.S. at 342, 125 S.Ct. 1627. More is required of plaintiffs—particular allegations as to "what the relevant economic loss might be," and "what the causal connection might be" between the fraud alleged and the economic losses actually suffered. *Id.* at 347, 125 S.Ct. 1627.

The complaint in this case is meaningfully different from that in *Dura Pharmaceuticals*. The Investors here identify a specific economic loss: the drop in value on October 29, 2003, that followed the October 28 press release. They also allege that this loss was caused by Gilead's misrepresentations.

They provide abundant details of Gilead's off-label marketing, and they assert that this led to higher demand for Viread, which in turn inflated Gilead's stock price.[6] As summarized in the complaint's introduction,

> [T]he market was not told that off-label marketing was the cornerstone of demand. This mistaken impression of demand led to, among other things, wholesaler overstocking in reaction to an anticipated price increase. When the truth about [Gilead's and the Officers'] off-label marketing was disclosed, however, [they] could no longer maintain the sales growth levels that investors had come to expect, and Gilead's stock price dropped accordingly.

Assuming, then, that the Investors' theory is sound and that they can prove all that they allege, the district court erred by holding that *Dura Pharmaceuticals* compelled dismissal of this action.

The dismissal order below, though, suggests that the district court was unwilling to make these assumptions. The district court found that the complaint contained "too many logical and factual gaps."

Based on our own review, we find the complaint sufficiently alleges a causal relationship between (1) the increase in sales resulting from the off-label marketing, (2) the Warning Letter's effect on Viread

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[6] The complaint includes one concrete example of how Gilead's stock price was directly inflated by Viread's sales performance: the 13.4% rise in share value triggered by Gilead's positive statements about demand for Viread on July 14, 2003, the first day of the class period.

orders, and (3) the Warning Letter's effect on Gilead's stock price.

Perhaps what truly motivated the dismissal was the district court's incredulity. The court expressly identified two allegations it was unwilling to accept. First, it could not make "the unreasonable inference that a public revelation on August 8 *caused* a price drop *three months later* on October 28." Order Granting Defs.' Mot. to Dismiss at 11. Second, with respect to the Warning Letter's impact on Viread sales, the court found "a slowing increase in demand, alone, too speculative to adequately demonstrate loss causation." *Id.* at 12 n. 10.

As an initial matter, we note that a district court ruling on a motion to dismiss is not sitting as a trier of fact. It is true that the court need not accept as true conclusory allegations, nor make unwarranted deductions or unreasonable inferences. *Sprewell*, 266 F.3d at 988. But so long as the plaintiff alleges facts to support a theory that is not facially implausible, the court's skepticism is best reserved for later stages of the proceedings when the plaintiff's case can be rejected on evidentiary grounds. "[A] well-pleaded complaint may proceed even if it strikes a savvy judge that actual proof of those facts is improbable, and that a recovery is very remote and unlikely." *Bell Atl. Corp. v. Twombly*, --- U.S. ---, 127 S.Ct. 1955, 1965, 167 L.Ed.2d 929 (2007) (internal quotation marks omitted).

There is no exception to this rule for the element of loss causation. The Third Circuit has stated that "loss causation becomes most critical at the proof stage," and has cited scholarly authority stating that it is normally inappropriate to rule on loss causation at the pleading stage. *McCabe v. Ernst &*

*Young, LLP*, 494 F.3d 418, 427 n. 4 (3rd Cir.2007) (internal quotation marks omitted). Similarly, the Second Circuit has held that loss causation "is a matter of proof at trial and not to be decided on a Rule 12(b)(6) motion to dismiss." *Emergent Capital Inv. Mgmt., LLC. v. Stonepath Group, Inc.*, 343 F.3d 189, 197 (2d Cir.2003). *But see Lentell v. Merrill Lynch & Co.*, 396 F.3d 161, 172-77 (2d Cir.2005) (failure to plead any facts supporting loss causation warranted 12(b)(6) dismissal of complaint).

We agree. So long as the complaint alleges facts that, if taken as true, plausibly establish loss causation, a Rule 12(b)(6) dismissal is inappropriate. This is not "a probability requirement . . . it simply calls for enough fact to raise a reasonable expectation that discovery will reveal evidence of" loss causation. *Bell Atl.*, 127 S.Ct. at 1965.

The district court's concern about the elapse of time between the public issuance of the Warning Letter and the drop in price recalls our holding in *No. 84 Employer-Teamster Joint Council Pension Trust Fund v. America West Holding Corp.*, 320 F.3d 920 (9th Cir.2003) (internal quotation marks omitted). There, a Rule 10b-5 defendant argued that its alleged misrepresentations were per se immaterial because the injurious drop in stock price took place more than one and a half months after the market learned the truth about the misrepresentations. *Id.* at 934. We rejected "a bright-line rule requiring an immediate market reaction" because "[t]he market is subject to distortions that prevent the ideal of a free and open public market from occurring." *Id.* (internal quotation marks omitted). Instead, we held that courts must engage

in a "fact-specific inquiry." *Id.* (internal quotation marks omitted).

We believe that *America West's* discussion of materiality applies with equal force to the loss causation requirement. A limited temporal gap between the time a misrepresentation is publicly revealed and the subsequent decline in stock value does not render a plaintiff's theory of loss causation per se implausible.

Our review of the Investors' complaint convinces us that the October drop in stock price was plausibly caused by the Warning Letter. Importantly, the drop occurred immediately after Gilead disclosed less-than-expected revenues resulting from the reduction in wholesalers' Viread inventories, which analysts ascribed to lower end-user demand. That lower end-user demand, in turn, is expressly alleged to have been caused by the Warning Letter. In this light, the market did react immediately to the corrective disclosure—the October 28 press release. The Warning Letter, which discussed only two instances of off-label marketing, would not necessarily trigger a market reaction because it did not contain enough information to significantly undermine Gilead's July 2003 pronouncements concerning demand for Viread. It is not unreasonable that physicians—the targets of the off-label marketing—would respond to the Warning Letter while the public failed to appreciate its significance.

The district court also erroneously concluded that a slowing increase in demand is too speculative to establish loss causation. Had the Investors alleged that the Warning Letter eliminated all sales resulting from off-label marketing, it would be very unlikely that demand would continue to increase,

since the complaint asserts that 75% to 95% of sales were caused by off-label marketing. But they do not allege that, and we see no reason why the court cannot proceed to the evidentiary stages to determine the extent of the Warning Letter's impact on the growth of demand for Viread.

The complaint specifically alleges that physicians were less eager to prescribe Viread, and competitors used the Warning Letter to lure Viread customers to other drugs. This is "enough fact to raise a reasonable expectation that discovery will reveal evidence"—or the lack thereof—of the Warning Letter's effect on demand. *Bell Atl.*, 127 S.Ct. at 1965.

## *CONCLUSION*

For the foregoing reasons, the district court improperly granted Gilead's and the Officers' Rule 12(b)(6) motion. The Investors have sufficiently alleged loss causation and economic loss. We leave it to the district court to determine whether they have sufficiently alleged the other elements of their claims.

*REVERSED* and *REMANDED*.

**APPENDIX B**

UNITED STATES DISTRICT COURT,
N.D. California.

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In re GILEAD SCIENCES SECURITIES LITIGATION.

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This Document Relates To All Actions.

Nos. C03-4999 MJJ, C03-5391 MJJ,
C04-0100 MJJ, C03-5088 MJJ,
C03-5592 MJJ, C03-5113 MJJ,
C03-5805 MJJ.

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May 12, 2006.

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ORDER *GRANTING* DEFENDANTS' 12(b)(6)
MOTION TO DISMISS

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MARTIN J. JENKINS, District Judge.

*INTRODUCTION*

Before the Court is Gilead Sciences, Inc. ("Gilead"), John C. Martin, John F. Milligan, Mark L. Perry, Norbert W. Bischofberger, Anthony Carrociolo and William A. Lee's ("Defendants") Motion to Dismiss a federal securities fraud action brought against them by a class consisting of all purchasers of Gilead stock between July 14, 2003 and October 28, 2003.[1] Defendants seek an order dismissing the Fourth Amended Class Action Complaint ("FAC") with prejudice under

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[1] Docket No. 140, filed on December 22, 2005.

the heightened pleading requirements of the Private Securities Litigation Reform Act of 1995 ("PSLRA") and pursuant to Federal Rules of Civil Procedure 12(b)(6) and 9(b). For the following reasons, the Court GRANTS Defendants' motion with prejudice.

## *BACKGROUND*

### *A. Factual History*

The FAC is brought on behalf of a class consisting of all persons who purchased or otherwise acquired Gilead stock between July 14, 2003 and October 28, 2003 (the "Class Period"). The allegations in the FAC relate to Gilead's announcement in July 2003 of its financial results for the second quarter of 2003, and the impact its premier product, Viread, had on those results. Viread is a antiretroviral drug used to treat HIV/AIDS that Gilead introduced in 2001. On July 14, 2003, the first day of the class period, Gilead issued a press release entitled "Gilead Sciences Expects Second Quarter 2003 Financial Results Will Exceed Expectations," and stating, "[t]he increase in revenue was driven primarily by strong sales growth of Viread." The press release went on to say that Viread sales increased due to "broader prescribing patterns . . . as well as increases in U.S. wholesaler inventory in the second quarter." On the same day, *Bloomberg News* identified Gilead spokeswoman Amy Flood as stating that "[t]he main reason for the jump in Viread sales is an increase in prescriptions, not inventory stocking."

Two weeks later, on July 31, 2003, Gilead issued a press release containing its final results for the second quarter. Gilead announced that it had net revenues of $230.7 million for the second quarter, of which $167 million related to Viread. Gilead went on:

> Viread sales growth was primarily driven by higher prescription volume, a significant increase in U.S. wholesaler inventories and a favorable European currency environment compared to the same quarter last year. Gilead estimates that increased stocking by U.S. wholesalers accounted for $25-30 million in Viread sales in the second quarter.

The press release contained warnings regarding the forward-looking statements and stated that the statements were "subject to certain risks and uncertainties, which could cause actual results to differ materially." Statements made during Gilead's earnings call of that same date, as well as on its Form 10-Q filed August 14, 2003, contained similar warnings.

Also on July 31, 2003, Gilead held a conference call with analysts and other investors regarding its financial results. During the call, an officer of Gilead stated:

> Of significant note, we believe that a substantial inventory build occurred in U.S. distributor channel during the second quarter as wholesalers anticipated the Viread price increase announced on June 27th. Though difficult to determine the exact figure for this inventory build, we estimate that wholesaler inventories increased by $25 to $30 million during the quarter. . . . Based on the U.S. inventory build up seen in the second quarter, we anticipate Viread sales for the third quarter will be at or below the sales level recognized this second quarter. We expect these inventories to be drawn down to more normal levels during this quarter.

According to the FAC, market analysts—including Morgan Stanley, Prudential, and Bear Stearns—continued to predict strong demand for Viread in the third quarter of 2003 despite the inventory overstock.

On August 14, 2003, Gilead filed its Form 10-Q for the second quarter of 2003. This form confirmed the previously announced financial results. The Form 10-Q also discussed the inventory build-up: "We estimate that this higher stocking resulted in $25.0 to $30.0 million of additional sales during the second quarter, which may adversely impact sales in the third quarter as wholesalers return to more normal inventory levels and buying patterns." The Form 10-Q also disclosed the existence of a July 29, 2003 letter issued by the FDA warning Gilead about certain aspects of its promotional practices of Viread.[2]

In its October 28, 2003 Press Release, Gilead announced its financial results for the third quarter of 2003, Gilead announced net revenues of $194.1 million, and sales of Viread of $115.4 million. At that time, Gilead stated: "After reviewing NDC prescription trends, IMS inventory data and actual Viread sales, Gilead estimates there was approximately $33 to $37 million of inventory reduction by U.S. pharmaceutical wholesalers during the third quarter of 2003 following an equivalent inventory build during the second quarter of 2003." The next day, Gilead's stock dropped $7.46 per share from $59.46 per share to close at $52 per share. Approximately one month later, on December 2, 2003, Gilead's stock price had recovered the entire drop experienced on October 29 and closed at $59.83 per share.

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[2] Gilead initially made the FDA letter public on August 7, 2003.

Plaintiffs allege that for the period of at least September 2001 through, and subsequent to, the class period, Gilead engaged in the off-label marketing of Viread. Off-label marketing refers to the use for marketing purposes of information such as the result of clinical studies and other material on the uses of and the efficacy of an FDA-approved product that has not been approved by the FDA for inclusion in the product's package labeling. Pursuant to FDA guidelines, pharmaceutical manufacturers such as Gilead may only promote an FDA-approved drug consistent with the contents of its FDA-approved package labeling. Plaintiffs assert that the off-label marketing took three forms: 1) marketing to HIV patients co-infected with Hepatitis B virus ("HBV"); 2) marketing Viread as a first-line or initial therapy for HIV infection; and 3) marketing against Viread's safety profile.

Plaintiffs allege that Gilead's off-label marketing activities began as early as September 2001 at Gilead's national sales meeting in Miami. There, sales and marketing employees allegedly were given information regarding Gilead's submission of Viread clinical data and information to the FDA and, with a "wink and a nod," were instructed to use this information to sell Viread even though Viread had yet to be approved by the FDA. The FDA approved Viread in October 2001.[3] Later, employees allegedly were instructed, "overtly and covertly," at numerous regional and national sales meetings by Gilead executives to use off-label information to aggressively promote and sell Viread.[4] At these meetings, employees

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[3] From October 2001 to August 2003, Viread's market share increased steadily from zero to nearly 20 percent.

[4] The FAC states that Plaintiffs' confidential witnesses (CW1 and CW2) attended various meetings at which Gilead's sales

allegedly would be provided off-label information such as updates on clinical trials of Viread on large group meetings and then told in subsequent smaller meetings to use this information to sell Viread. Defendants Martin, Perry, Lee, Milligan, and Bischofberger allegedly attended one or more of these regional and national sales meetings.

According to the FAC, Gilead received an Untitled FDA Letter on March 14, 2002, advising the company that its representatives had made false and misleading oral promotional statements at the December 2001 Interscience Conference on Antimicrobial Agents and Chemotherapy conference. According to the Untitled FDA Letter, Gilead falsely and misleadingly promoted Viread by stating that it contained "no toxicities," was "extremely safe," and was "extremely well-tolerated," despite the fact that its boxed warning and Package Labeling advised to the contrary. The Untitled FDA Letter further ordered Gilead to "immediately cease making such violative statements," and required Gilead to submit a written response describing its intent and plans to comply with the FDA's directives. Plaintiffs allege that the false statements were made by Defendant Martin and it was company-wide knowledge that Martin was the cause of the Untitled FDA Letter.

On March 21, 2002, Gilead responded saying that it was "commit[ted] to ensure that future violative statements are not made in the promotion of Viread." However, sixteen months later, on July 29, 2003, the

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and marketing team received specific instructions to market Viread off-label. According to CW1, 85% to 95% of his Viread sales were a result of off-label marketing. Plaintiffs also allege that 85% to 90% of CW2's Viread sales were a result of off-label marketing.

FDA issued a second letter ("FDA Warning Letter") notifying Gilead that it considered certain oral representations made by a Gilead representative at a promotion booth during a conference call in April 2003 to be improper. This conference took place during Gilead's second fiscal quarter of 2003, just prior to Defendants' first class period announcement of outstanding Viread sales and financial results which exceeded market expectations.

This second FDA letter became public on August 7, 2003. According to the FAC, investors did not attribute much significance to the letter. (FAC at ¶ 191.) In response to the FDA letter on November 7, 2003, defendant Martin wrote a correction letter to the conference attendees.

Plaintiffs allege that Defendants provided so many off-label instructional materials and were so forceful in promoting off-label use, that 75% to 95% of Viread sales were attributable to off-label promotion. According to the FAC, this accounted for between $86.7 million and $109.82 million of Gilead's second quarter 2003 domestic Viread sales. (FAC at ¶ 150.) Plaintiffs allege that Defendants maintained this misleading image of Viread for a long enough period for the stock price to become inflated and for Defendants to sell their shares before the FDA made their second letter to Gilead public.

*B. Procedural History*

On January 25, 2005, the Court dismissed Plaintiffs' Consolidated Amended Complaint ("CAC") with leave to amend, finding that Plaintiffs failed to establish the requisite connection between Gilead's off-label marketing activities and the allegedly false 2003 second quarter reports. Plaintiffs filed the Third

Consolidated Amended Class Action Complaint ("TAC") on March 11, 2005.[5] On October 11, 2005 the Court dismissed Plaintiffs' TAC with leave to amend ("Order"). Once again the Court found Plaintiffs' pleadings deficient. Although the Court voiced its concerns as to whether Plaintiffs adequately demonstrated that the off-label marketing scheme "materially" affected Gilead's sales or stock price, it did not reach that issue on the merits. Instead the Court found Plaintiffs' pleadings deficient because they failed to allege loss causation in light of *Dura Pharmaceuticals, Inc. v. Broudo*, 125 S.Ct. 1627 (2005),[6] and *In re Daou Systems, Inc.*, 411 F.3d 1006 (9th Cir.2005).[7] The Court held "in light of *Dura*, it is evident that Plaintiffs have not adequately alleged proximate causation and economic loss with respect to Gilead's alleged off-label marketing scheme." (Order at 12:21-23.) The Court ruled that "Plaintiffs [did] not allege that a price drop immediately accompanied the disclosure of the FDA [W]arning [L]etter, and hence the Court is left to speculate as to what portion of the eventual loss, if any, should be attributed to the disclosure or whether the loss was caused by

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[5] Plaintiffs filed their Second Consolidated Amended Class Action Complaint on February 25, 2005 (Docket No. 99), which they amended shortly thereafter with the TAC.

[6] The Supreme Court decided *Dura* after the Court dismissed the CAC. *Dura* held that in order to demonstrate loss causation, plaintiffs must establish an actual "causal connection" between the defendants' material misrepresentation and the economic loss suffered. *Dura*, 125 S.Ct. at 1631-33.

[7] The Ninth Circuit decided *Daou* after the Court dismissed the CAC as well. There, the Ninth Circuit held that a plaintiff sufficiently pleads "loss causation" by alleging that there was a steep drop in defendants' stock price upon revelation of previously undisclosed facts. *Daou*, 411 F.3d at 1026.

other factors." (Order at 12:23-26.) Plaintiffs filed the FAC on December 2, 2005 in response to the Order.

*JUDICIAL NOTICE*

In addition to the Motion to Dismiss the FAC, Defendants have filed a Request for Judicial Notice, and ask the Court to notice a number of documents. Federal Rule of Evidence 201 allows a court to take judicial notice of a fact "not subject to reasonable dispute in that it is . . . capable of accurate and ready determination by resort to sources whose accuracy can[ ]not reasonably be questioned." Plaintiffs do not object to the Court's taking judicial notice of the requested documents. The Court finds taking judicial notice of those documents and all other requested documents appropriate here. *Branch v. Tunnell*, 14 F.3d 449, 454 (9th Cir.1994), *cert. denied*, 512 U.S. 1219 (1997); *In re Calpine Corp. Sec. Lit.*, 288 F.Supp.2d 1054, 1076 (N.D.Cal.2003). Accordingly, the Court takes notice of all such documents.[8]

*LEGAL STANDARDS*

*A. Rule 12(b)(6)*

A court may dismiss a complaint pursuant to Federal Rule of Civil Procedure 12(b)(6) for either lack of a cognizable legal theory or the pleading of insufficient facts under an adequate theory. *Robertson v. Dean Witter Reynolds, Inc.*, 749 F.2d 530, 533-34 (9th Cir.1984). When deciding upon a motion to dismiss for failure to state a claim upon which relief can be granted pursuant to Rule 12(b)(6), a court must take

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[8] In its order dismissing the CAC the Court judicially noticed several of the documents for which Defendants ask for judicial notice in this motion to dismiss. (Amended Order Granting Defendants' 12(b)(6) Motion To Dismiss, 5:20-21.)

all of the material allegations in the plaintiff's complaint as true, and construe them in the light most favorable to the plaintiff. *Parks School of Business, Inc. v. Symington*, 51 F.3d 1480, 1484 (9th Cir.1995). Moreover, a complaint should not be dismissed unless the plaintiff could prove no set of facts in support of his claim that would entitle that plaintiff to relief. *Id.*

In the context of a motion to dismiss, review is limited to the contents of the complaint. *Allarcom Pay Television, Ltd. v. General Instrument Corp.*, 69 F.3d 381, 385 (9th Cir.1995). When matters outside the pleading are presented to and accepted by the court, the motion to dismiss is converted into one for summary judgment. Where such a conversion takes place, all parties must be given an opportunity to present all material made pertinent to such a motion by Rule 56. *In re Pacific Gateway Exchange, Inc. Sec. Lit.*, 169 F.Supp.2d 1160, 1164 (N.D.Cal.2001); *see also* Fed.R.Civ.P. 12(b). However, matters properly presented to the court, such as those attached to the complaint and incorporated within its allegations, may be considered as part of the motion to dismiss. *See Hal Roach Studies, Inc. v. Richard Feiner & Co.*, 896 F.2d 1542, 1555 n 19 (9th Cir.1989).

Where a plaintiff fails to attach to the complaint documents referred to in it, and upon which the complaint is premised, a defendant may attach to the motion to dismiss such documents in order to show that they do not support the plaintiff's claim. *See Pacific Gateway Exchange*, 169 F.Supp.2d at 1164; *Branch*, 14 F.3d at 454. Thus, the district court may consider the full texts of documents that the complaint only quotes in part. *See In re Stac Electronics Sec. Lit.*, 89 F.3d 1399, 1405 n. 4 (1996), *cert. denied*, 520 U.S. 1103 (1997). This rule precludes a plaintiff "from sur-

viving a Rule 12(b)(6) motion by deliberately omitting references to documents upon which [the] claims are based." *Parrino v. FHP, Inc.*, 146 F.3d 699, 706 (9th Cir.1998).

*B. Section 10(b) And Rule 10b-5*

Section 10(b) of the Securities Exchange Act ("Act") provides, in part, that it is unlawful "to use or employ in connection with the purchase or sale of any security registered on a national securities exchange or any security not so registered, any manipulative or deceptive device or contrivance in contravention of such rules and regulations as the [SEC] may prescribe." 15 U.S.C. § 78j(b).

Rule 10b-5 makes it unlawful for any person to use interstate commerce

> (a) to employ any device, scheme, or artifice to defraud;
>
> (b) to make any untrue statement of material fact or to omit to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading; or
>
> (c) to engage in any act, practice, or course of business which operates or would operate as a fraud or deceit upon any person, in connection with the purchase or sale of any security.

17 C.F.R. § 240.10b-5.

To be actionable under section 10(b) and Rule 10b-5, a plaintiff must allege 1) a misrepresentation or omission; 2) of material fact; 3) made with scienter; 4) on which the plaintiff justifiably relied; 5) that proximately caused the alleged loss. *See Binder v. Gillespie*, 184 F.3d 1059, 1063 (9th Cir.1999). Addi-

tionally, as in all actions alleging fraud, plaintiffs must state with particularity the circumstances constituting fraud. Fed.R.Civ.P. 9(b).

*C. Section 20(a)*

Section 20(a) of the Act provides derivative liability for those who control others found to be primarily liable under the Act. *In re Ramp Networks, Inc. Sec. Lit.*, 201 F.Supp.2d 1051, 1063 (N.D.Cal.2002). Where a plaintiff asserts a section 20(a) claim based on an underlying violation of section 10(b), the pleading requirements for both violations are the same. *Id.*

*D. Private Securities Litigation Reform Act*

In 1995, Congress enacted the PSLRA to provide "protections to discourage frivolous [securities] litigation." H.R. Conf. Rep. No. 104-469, 104th Conf., 1st Sess. at 32 (1995) (Nov. 28, 1995). The PSLRA strengthened the pleading requirements of Rules 8(a) and 9(b). Actions based on allegations of material misstatements or omissions under the PSLRA must "specify each statement alleged to have been misleading, the reason or reasons why the statement is misleading, and, if an allegation regarding the statement or omission is made on information and belief, the complaint shall state with particularity all facts on which that belief is formed." 15 U.S.C. § 78u-4(b)(1).

The PSLRA also heightened the pleading threshold for causes of action brought under Section 10(b) and Rule 10b-5. Specifically, the PSLRA imposed strict requirements for pleading scienter. A complaint under the PSLRA must "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." 15 U.S.C. § 78u-4(b)(2). The Ninth Circuit, in interpreting the

PSLRA, has held that "a private securities plaintiff proceeding under the [PSLRA] must plead, in great detail, facts that constitute strong circumstantial evidence of deliberately reckless or conscious misconduct." *In re Silicon Graphics, Inc. Sec. Lit.*, 183 F.3d 970, 974 (9th Cir.1999). If the complaint does not satisfy the pleading requirements of the PSLRA, upon motion by the defendant, the court must dismiss the complaint. *See* 15 U.S.C. § 78u-4(b)(1).

*ANALYSIS*

After the Court dismissed Plaintiffs' TAC for failure to adequately allege loss causation, Plaintiffs amended their complaint on December 2, 2005. Plaintiffs' amendments primarily consist of allegations that market analysts predicted an increase in Gilead's sales despite the overstock of Viread. Again, Plaintiffs rely on three types of allegations to support their Section 10(b) action: 1) Defendants' statements and omissions regarding wholesaler overstocking; 2) the alleged financial impact of the off-label marketing scheme; and 3) the individual Defendants' own stock sales. Defendants move the Court to dismiss the FAC with prejudice pursuant to the PSLRA and Federal Rules of Civil Procedure 9(b) and 12(b)(6), arguing that Plaintiffs fail to adequately plead loss causation, falsity, and scienter.

*A. Loss Causation*

Allegations of "loss causation" are a necessary element of a § 10(b) claim. *Dura*, 125 S.Ct. at 1631. Merely alleging that a misrepresentation caused an inflated purchase price does not, without more, demonstrate loss causation. *Id.* at 1631-32. It is insufficient for a misrepresentation to "touch upon" an economic loss; a plaintiff must demonstrate an actual

"causal connection" between the defendant's material misrepresentation and the economic loss suffered. *Id.* at 1632. In other words, "to prove loss causation, the plaintiff must demonstrate a causal connection between the deceptive acts that form the basis for the claim of securities fraud and the injury suffered by the plaintiff." *Daou*, 411 F.3d at 1025.

Defendants argue that Plaintiffs still have not established a "causal connection" between the disclosure of the FDA's warning letter (containing the off-label marketing allegations) and the drop in Gilead's stock price. Defendants contend that the additional information provided in the FAC has added little to Plaintiffs' previous complaint, which insufficiently pled loss causation.

In support of their position, Plaintiffs point to the following allegations from the FAC: 1) Defendants' alleged off-label marketing caused increased prescriptions and sales, which caused legitimate demand due to "explosive growth"; 2) Defendants' scheme was followed by the FDA Warning Letter forbidding Gilead from engaging in off-label marketing; and 3) this letter caused a slow down in demand for Viread, which in turn caused a slow down in sales, resulting in a stock price decline. According to Plaintiffs, the resulting slow down in sales and consequential stock decline was "foreseeable and well within the 'zone of risk' concealed by Defendants' [off-label marketing]." (Plaintiffs' Corrected Memorandum of Points and Authorities in Opposition to Motion to Dismiss FAC at 17:17.)

As the Court found in its previous order, Plaintiffs' allegations regarding loss causation are simply too attenuated. Plaintiffs continue to allege that the disclosure of the August 8, 2003 FDA Warning Letter

coupled with the announcement of disappointing sales in the October 28, 2003 Press Release shocked investors and caused the price of Gilead stock to drop.[9] To satisfy the loss-causation requirement, Plaintiffs must allege that the material misrepresentation caused their loss. The fundamental problem with Plaintiffs' allegations is that they require the Court to make the unreasonable inference that a public revelation on August 8 *caused* a price drop *three months later* on October 28. There was no price drop immediately after the August 8 revelation. The new allegations in Plaintiffs' FAC merely reinforce the Court's finding regarding the reasonableness of this inference and do little to meet their loss causation pleading burden.

Several of Plaintiffs' new allegations require the Court to make unwarranted inferences that the FDA Warning Letter was the cause of the lower demand for Viread. Plaintiffs attempt to support these allegations with citations to general conclusions in market analyst reports by Morgan Stanley, Prudential, and Bear Stearns. Neither the new allegations nor the market analyst reports help Plaintiffs' loss causation claim. First, Plaintiffs' assertion that the FDA Warning Letter was the cause of the lower demand for Viread still does not establish a causal connection. Even if the FDA Warning Letter caused practitioners to reduce their Viread supply, Plaintiffs still fail to connect that with the drop in stock price.

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[9] The Court noted in its Order that "this argument is flawed because the record reflects that investors never actually learned the extent of Defendants' off-label marketing scheme." (Order Granting Motion to Dismiss at 12:18-19, Doc. No. 136).

Additionally, the Court finds the market analyst reports problematic because they undermine Plaintiffs' theory that the disclosure led to a decrease in demand. The reports do not predict a decrease in demand at all. Indeed, they suggest that the demand for Viread would continue to grow. (Defendants' Motion to Dismiss FAC at Ex. G.) Further, the reports simply restated what Gilead had already stated in its October 28, 2003 Press Release—that Viread would expect lower end-user demand during the third quarter due to higher than normal inventories entering that quarter. (Defendants' Motion to Dismiss FAC at Ex. G, I.) Thus, the Court finds that the market analyst reports do not shed any new light on the loss causation issue.[10]

Plaintiffs correctly argue that the heightened pleading standard does not apply to allegations that Defendants' misrepresentations caused their loss. *Dura*, 125 S.Ct at 1633-34. However, Plaintiffs reliance on *In re Parmalat Sec. Litigation*, 375 F.Supp.2d 278 (S.D.N.Y.2005), and *Teamsters Local 445 Freight Div. Pension Fund v. Bombardier Inc.*, 2005 U.S. Dist. LEXIS 19506 (S.D.N.Y. Sept 6, 2005), to support the proposition that merely alleging a corrective disclosure followed by a decline in stock price is sufficient to plead loss causation, is misplaced. The Court finds this case distinguishable from *Parmalat* and *Teamsters* as the price drop in those cases occurred soon after the revelation of the misrepresentation.[11]

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[10] Defendants concede the demand for Viread did not increase at the same rate in the third quarter. The Court, however, finds a slowing increase in demand, alone, too speculative to adequately demonstrate loss causation.

[11] The Court has reviewed the other cases to which Plaintiffs cite and finds them equally distinguishable.

*Parmalat* involved a drop in securities price after disclosure of a fraud that understated Parmalat's debt by virtually $10 billion and overstated the corporation's assets by over $16 billion. *Parmalat*, 375 F.Supp.2d at 282. To support their allegations of securities fraud, the plaintiffs alleged that the company's auditor, Delcitte, issued two financial reports with the understated debts and overstated assets. *Id.* at 307. About eighteen months later, Parmalat was unable to repay its bonds when they became due and publicly disclosed that a $4.9 billion bank account it supposedly held did not exist. *Id.* at 284. This was immediately followed by a drop in stock price. *Id.* at 307. There the district court found the plaintiffs adequately pled loss causation because the "[d]efendants reasonably could have foreseen that Parmalat's inability to service its debt would lead to a financial collapse." *Id.*

Similarly, the plaintiff in *Teamsters* alleged senior management of Bombardier Capital Inc. ("BCI"), a manufactured housing asset-backed company, disregarded the companies' underwriting standards in favor of high-risk loans. *Teamsters*, 2005 U.S. Dist. LEXIS 19506, at *7. BCI did not disclose on its Form 8-K filing or otherwise its actual underwriting practices and thus concealed the high-risk loans. *Id.* at *6. The high-risk loans turned into "bad loans" and resulted in a sharp increase in delinquencies and foreclosure on BCI assets. *Id.* at *8. As a result, BCI's stock certificates suffered a price decrease of 38% in less than three months. *Id.* at *7. There the district court found the plaintiff adequately alleged loss causation:

> Plaintiff has alleged that its loss was caused when a risk that was concealed by the defen-

> dants materialized in a foreseeable chain of events. The Complaint alleges that defendants' misrepresentations regarding rigorous underwriting concealed the fact that the collateral pool contained a substantial number of high risk loans. The concealed risk materialized when the collateral pool experienced high delinquency rates and repossession on a sustained basis. Not surprisingly, BCI's earnings expectations then fell. BCI announced that it would write off the losses, rating agencies downgraded the Certificates, and the value of plaintiff's investment declined. These allegations are sufficient to plead loss causation.

*Id.* at *57.

The case before the Court, however, is substantially different. Both *Parmalat* and *Teamsters* involved the omission and subsequent disclosure of substantial corporate debt that clearly related to the decline in stock value. A fundamental principle of causation is "that the injury averred must proceed directly from the wrong alleged and must not be attributable to some supervening cause."[12] *Marbury Mgmt., Inc. v. Kohn*, 629 F.2d 705, 716-17 (2d

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[12] There are too many logical and factual gaps in Plaintiffs' allegations to support the conclusion that Defendants' alleged misconduct proximately caused Gilead's stock decrease in October. *Dura*, 125 S.Ct. at 1632. The FAC does not connect the following chain of events, which it must for Plaintiffs to adequately plead loss causation: 1) that Defendants' alleged failure to disclose the off-label marketing scheme caused a material increase in sales; 2) that practitioners materially decreased their demand for Viread due to the publication of the FDA Warning Letter; and most importantly, 3) that the alleged decrease in sales due to the FDA letter proximately caused Gilead's stock to decrease three months later.

Cir.1980) (Meskill, J., dissenting). It is worth reiterating that the FDA letter became public on August 7, 2003, and the loss which that revelation allegedly caused occurred nearly *three months* later on October 29, 2003. Consequently, the Court is left to speculate as to what portion, if any, of that decrease should be attributed to the alleged misconduct and what should be attributed to other market factors. A court need not indulge unwarranted inferences in determining whether a plaintiff has adequately pled a necessary element. *In re Verifone Sec. Lit.*, 11 F.3d 865, 868 (9th Cir.1993). Even viewed in the light most favorable to Plaintiffs,[13] the Court finds that Plaintiffs have not adequately pled, under *Dura*, that the alleged misrepresentation proximately caused their loss.[14] Accordingly, the Court must dismiss the Complaint.[15]

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[13] The Court must consider all reasonable inferences to be drawn from the allegations, "including inferences unfavorable to the plaintiffs." *Gompper v. VISX, Inc.*, 298 F.3d 893, 897 (9th Cir. 2002).

[14] The Court distinguishes this case from *Daou*. In *Daou*, the defendants fraudulently inflated their stock price through accounting methods which violated Generally Accepted Accounting Practices. *Daou*, 411 F.3d at 1012. There, the Ninth Circuit found loss causation because plaintiffs alleged a steep drop in stock price following disclosure of Defendants' "true financial health." *Id.* at 1026. Here, however, Plaintiffs have not adequately connected the disclosure of Gilead's off-label marketing and the drop in stock price in the FAC. Indeed, the evidence Plaintiffs have presented to the Court only supports an inference that the market gave little or no weight to the FDA Warning Letter.

[15] Because Plaintiffs have not adequately alleged loss causation, the Court need not consider whether Plaintiffs have adequately alleged falsity or scienter.

*B. Rule 20(a) Liability*

Section 20(a) of the Securities Exchange Act provides derivative liability for those who control others found to be primarily liable under the Act. *In re Ramp Networks, Inc. Sec. Lit.*, 201 F.Supp.2d at 1063. Where a plaintiff asserts a Section 20(a) claim based on an underlying violation of Section 10(b), the pleading requirements for both violations are the same. *Id.* Because Plaintiffs have failed to adequately plead the underlying 10b-5 violation, the Section 20(a) claims must be dismissed against the individual Defendants as well.

*C. Dismissal With Prejudice*

A court considers five factors in determining whether to dismiss a complaint with prejudice: 1) bad faith, 2) undue delay, 3) prejudice to the opposing party, 4) futility of the amendment, and 5) whether plaintiff has previously amended his complaint. *Allen v. City of Beverly Hills*, 911 F.2d 367, 373 (9th Cir. 1990). A court's "discretion to deny leave to amend is particularly broad where plaintiff has previously amended the complaint." *Id.* (quoting *Ascon Properties, Inc. v. Mobil Oil Co.*, 866 F.2d 1149, 1160 (9th Cir.1989)).

Plaintiffs have filed four amended complaints, and this is the third complaint that the Court has dismissed. The Court found that Plaintiffs failed to allege with the requisite detail, falsity and scienter, when it dismissed Plaintiffs' CAC with leave to amend. The Court dismissed the TAC for failure to adequately plead loss causation, but it reiterated its concerns regarding the sufficiency of Plaintiffs' falsity and scienter allegations. Because *Daou* was decided after Plaintiffs filed their TAC, the Court again

granted leave to amend with respect to the issue of loss causation. Yet Plaintiffs still have not adequately alleged loss causation after having had another opportunity to do so. Since Plaintiffs have failed to remedy the deficiencies of their allegations in each amended version, the Court finds that further amendment is futile. Accordingly, the Court DISMISSES the Complaint *with prejudice*.

*CONCLUSION*

After consideration of the FAC in light of *Dura* and the requirements of Federal Rule of Civil Procedure 12(b)(6), the Court GRANTS Defendants' 12(b)(6) Motion to Dismiss the FAC with prejudice.[16] The Clerk of the Court is directed to close this case.

*IT IS SO ORDERED.*

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[16] Docket No. 140, filed December 22, 2005.

# APPENDIX C

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF
CALIFORNIA

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No. C 03-4999 MJJ

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In re GILEAD SCIENCES SECURITIES LITIGATION

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This Document Relates To: ALL ACTIONS

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ORDER *GRANTING* DEFENDANTS' 12(b)(6)
MOTION TO DISMISS

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## INTRODUCTION

Before the Court is Gilead Sciences, Inc. ("Gilead"), John C. Martin, John F. Milligan, Mark L. Perry, Norbert W. Bischofberger, Anthony Carrociolo and William A. Lee's ("Defendants") Motion to Dismiss a federal securities fraud action brought against them by a class consisting of all purchasers of Gilead stock between July 14, 2003 and October 28, 2003. Defendants seek an Order dismissing the Third Amended Class Action Complaint ("TAC") with prejudice under the heightened pleading requirements of the Private Securities Litigation Reform Act of 1995 ("PSLRA") and pursuant to Federal Rules of Civil Procedure 12(b)(6) and 9(b). For the following reasons, Defendants' motion is GRANTED with leave to amend.

## BACKGROUND

### A. Factual History

The TAC is brought on behalf of a class consisting of all persons who purchased or otherwise acquired Gilead stock between July 14, 2003 and October 28, 2003. The allegations in the TAC relate to Gilead's announcement in July 2003 of its financial results for the second quarter of 2003, and the impact its premier product, Viread, had on those results. Viread is a groundbreaking antiretroviral drug used to treat HIV/AIDS that was introduced in 2001, On July 14, 2003, the first day of the class period, Gilead issued a press release entitled "Gilead Sciences Expects Second Quarter 2003 Financial Results Will Exceed Expectations," and stating, "[t]he increase in revenue was driven primarily by strong sales growth of Viread." The press release went on to say that Viread sales increased due to "broader prescribing patterns. . . as well as increases in U.S. wholesaler inventory levels in the second quarter." On the same day, *Bloomberg News* identified Gilead spokeswoman Amy Flood as stating that "[t]he main reason for the jump in Viread sales is an increase in prescriptions, not inventory stocking."

Two weeks later, on July 31, 2003, Gilead issued a press release containing its final results for the second quarter. Gilead announced that it had net revenues of $230.7 million for the quarter, of which $167 million related to Viread. Gilead went on:

> Viread sales growth was primarily driven by higher prescription volume, a significant increase in U.S. wholesaler inventories and a favorable European currency environment compared to the same quarter last year. Gilead estimates that

> increased stocking by U.S. wholesalers accounted for $25-30 million in Viread sales in the second quarter.

The press release contained warnings regarding the forward-looking statements and stated that the statements were "subject to certain risks and uncertainties, which could cause actual results to differ materially." Statements made during Gilead's earnings call of that same date, as well as on its Form 10-Q filed August 14, 2003, contained similar warnings.

Also on July 31, 2003, Gilead held a conference call with analysts and other investors regarding its financial results. During the call, an officer of Gilead stated:

> Of significant note, we believe that a substantial inventory build occurred in U.S. distributor channel during the second quarter as wholesalers anticipated the Viread price increase announced on June 27th. Though difficult to determine the exact figure for this inventory build, we estimate that wholesaler inventories increased by $25 to $30 million during the quarter . . . . Based on the U.S. inventory build up seen in the second quarter, we anticipate Viread sales for the third quarter will be at or below the sales level recognized this second quarter. We expect these inventories to be drawn down to more normal levels during this quarter.

On August 14, 2003, Gilead filed its Form 10-Q for the second quarter of 2003. This form confirmed the previously announced financial results. The Form 10-Q also discussed the inventory build-up: "We estimate that this higher stocking resulted in $25.0 to $30.0 million of additional sales during the second

quarter, which may adversely impact sales in the third quarter as wholesalers return to more normal inventory levels and buying patterns." The form 10-Q also disclosed the existence of a July 29, 2003 letter issued by the FDA warning Gilead about certain aspects of its promotional practices of Viread.[1]

On October 28, 2003, Gilead announced its financial results for the third quarter of 2003. Gilead announced net revenues of $194.1 million, and sales of Viread of $115.4 million. At that time, Gilead stated: "After reviewing NDC prescription trends, IMS inventory data and actual Viread sales, Gilead estimates there was approximately $33 to $37 million of inventory reduction by U.S. pharmaceutical wholesalers during the third quarter of 2003 following an equivalent inventory build during the second quarter of 2003." The next day, Gilead's stock dropped $7.46 per share from $59.46 per share to close at $52 per share. Approximately one month later, on December 2, 2003, Gilead's stock price had recovered the entire drop experienced on October 29 and closed at $59.83 per share.

Plaintiffs allege that for the period of at least September 2001 through, and subsequent to, the class period, Gilead engaged in the off-label marketing of Viread. Off-label marketing refers to the use for marketing purposes of information such as the result of clinical studies and other materials on the uses of and the efficacy of an FDA-approved product that has not been approved by the FDA for inclusion in the product's package labeling. Pursuant to FDA guidelines, pharmaceutical manufacturers such as Gilead

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[1] Gilead initially made the FDA letter public on August 7, 2003.

may only promote an FDA-approved drug consistent with the contents of its FDA-approved package labeling. Plaintiffs assert that the off-label marketing took three forms: 1) marketing to HIV patients co-infected with Hepatitis B virus ("HBV"); 2) marketing Viread as a first-line or initial therapy for HIV infection, and 3) marketing against Viread's safety profile.

Plaintiffs allege that Gilead's off-label marketing activities began as early as September 2001 at Gilead's national sales meeting in Miami. There, sales and marketing employees allegedly were given information regarding Gilead's submission of Viread clinical data and information to the FDA and, with a "wink and a nod," were instructed to use this information to sell Viread even though Viread had yet to be approved by the FDA. The FDA approved Viread in October 2001. Later, employees allegedly were instructed at numerous regional end national sales meetings by Gilead executives "overtly and covertly," to use off-label information to aggressively promote and sell Viread.[2] At these meetings, employees allegedly would be provided off-label information such as updates on clinical trials of Viread in large group meetings and then told in subsequent smaller meetings to use this information to sell Viread. Defendants Martin, Perry, Lee, Milligan, and Bischofberger allegedly attended one or more of these regional and national sales meetings.

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[2] The TAC states that Plaintiffs' confidential witnesses (CW1 and CW2) attended various meetings at which Gilead's sales and marketing team received specific instructions to market Viread off-label. According to CW1, 85% to 95% of his Viread sales were a result of off-label marketing. Plaintiffs also allege that 85% to 90% of CW2's Viread sales were a result of off-label marketing.

According to the TAC, Gilead received an Untitled FDA Letter on March 14, 2002, advising the company that its representatives had made false and misleading oral promotional statements at the December 2001 Interscience Conference on Antimicrobial Agents and Chemotherapy conference. According to the Untitled FDA Letter, Gilead falsely and misleadingly promoted Viread by stating that it contained "no toxicities," was "extremely safe," and was "extremely well tolerated," despite the fact that its boxed warning and Package Labeling advised to the contrary. The Untitled FDA Letter further ordered Gilead to "immediately cease making such violative statements," and required Gilead to submit a written response describing its intent and plans to comply with the FDA's directives. Plaintiffs allege that the false statements were made by Defendant Martin and it was company-wide knowledge that Martin was the cause of the Untitled FDA Letter.

On March 21, 2002, Gilead responded stating that it was "commit[ted] to ensure that future violative statements are not made in the promotion of Viread." However, sixteen months later, on July 29, 2003, the FDA issued a second letter notifying Gilead that it considered certain oral representations made by a Gilead representative at a promotional booth during a conference in April 2003 to be improper. This conference took place during Gilead's second fiscal quarter of 2003, just prior to Defendants' first class period announcement of outstanding Viread sales and financial results which exceeded market expectations. In response to and in compliance with this letter, on November 7, 2003, defendant Martin wrote a correction letter to the conference's attendees.

Plaintiffs allege that Defendants provided so much off-label material and were so forceful in instructing off-label information that 75% to 95% of Viread sales arose from off-label promotion. According to the TAC, Gilead's second quarter 2003 domestic Viread sales were overstated by approximately $95 million due to off-label marketing.

B. Procedural History

On January 25, 2005, the Court dismissed Plaintiffs' Consolidated Amended Complaint ("CAC") with leave to amend ("the Order"). The Court found that Plaintiffs failed to "establish a connection between the company's off-label marketing activities and the 2003 second quarter reports that Plaintiffs allege were false and misleading." (Order at 13:17-19.) The Court ruled that to establish such a connection, "Plaintiffs must allege that Gilead's off-label marketing scheme was a 'material fact' that needed to be disclosed to investors along with the 2003 second quarter sales reports." (Order at 13:19-21.) The Court also found that "Plaintiffs have not alleged any sales of Viread during the second quarter of 2003 were the result of improper off-label marketing activities." (Order at 13:22-23.) The Court noted that "Plaintiffs must allege facts that show a relationship between the off-label marketing of Viread, related sales of Viread, and the manner in which those sales affected Gilead's 2003 second quarter financial reports." (Order at 14:6-8.) Plaintiffs filed the TAC on March 11, 2005 in response to the Court's directives in the Order.

## LEGAL STANDARDS

A. Rule 12(b)(6)

A court may dismiss a complaint pursuant to Federal Rule of Civil Procedure 12(b)(6) for either lack of

a cognizable legal theory or the pleading of insufficient facts under an adequate theory *Robertson v. Dean Witter Reynolds, Inc.*, 749 F.2d 530, 533-34 (9th Cir. 1984). When deciding upon a motion to dismiss for failure to state a claim upon which relief can be granted pursuant to FRCP 12(b)(6), a court must take all of the material allegations in plaintiff's complaint as true, and construe them in the light most favorable to plaintiff. *Parks School of Business, Inc. v. Symington*, 51 F.3d 1480, 1484 (9th Cir. 1995). Moreover, a complaint should not be dismissed unless a plaintiff could prove no set of facts in support of his claim that would entitle him to relief. *Id.*

In the context of a motion to dismiss, review is limited to the contents in the complaint. *Allarcom Pay Television, Ltd. v. General Instrument Corp.*, 69 F.3d 381, 385 (9th Cir. 1995). When matters outside the pleading are presented to and accepted by the court, the motion to dismiss is converted into one for summary judgment. Where such a conversion takes place, all parties must be given an opportunity to present all material made pertinent to such a motion by Rule 56. *In re Pacific Gateway Exchange, Inc. Sec. Lit.*, 169 F. Supp. 2d 1160, 1164 (N.D. Cal. 2001); *see also* Fed. R. Civ. P. 12(b), However, matters properly presented to the court, such as those attached to the complaint and incorporated within its allegations, may be considered as part of the motion to dismiss. *See Hal Roach Studios, Inc. v. Richard Feiner & Co.*, 896 F.2d 1542, 1555 n.19 (9th Cir. 1989).

Where a plaintiff fails to attach to the complaint documents referred to in it, and upon which the complaint is premised, a defendant may attach to the motion to dismiss such documents in order to show that they do not support plaintiff's claim. *See Pacific*

*Gateway Exchange*, 169 F. Supp. 2d at 1164; *Branch v. Tunnel*, 14 F.3d 449, 44 [sic] (9th Cir. 1994), *cert. denied*, 512 U.S. 1219 (1997). Thus, the district court may consider the full texts of documents that the complaint only quotes in part. *See In re Slay Electronics Sec. Lit.*, 89 F.3d 1399, 1405 n.4 (1996), *cert denied*, 520 U.S. 1103 (1997). This rule precludes plaintiffs "from surviving a Rule 12(b)(6) motion by deliberately omitting references to documents upon which their claims are based." *Parrino v. FHP, Inc.*, 146 F.3d 699, 705 (9th Cir. 1998).

B. Section 10(b) and Rule 10b-5

Section 10(b) of the Securities Exchange Act provides, in part, that it is unlawful "to use or employ in connection with the purchase or sale of any security registered on a national securities exchange or any security not so registered, any manipulative or deceptive device or contrivance in contravention of such rules and regulations as the [SEC] may prescribe." 15 U.S.C. § 78j(b).

Rule 10b-5 makes it unlawful for any person to use interstate commerce

> (a) To employ any device, scheme, or artifice to defraud.
>
> (b) To make any untrue statement of material fact or to omit to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading, or
>
> (c) To engage in any act, practice, or course of business which operates or would operate as a fraud or deceit upon any person, in connection with the purchase or sale of any security.

17 C.F.R. § 240.10b-5

To be actionable under section 10(b) and Rule 10b-5, a plaintiff must allege (1) a misrepresentation or omission; (2) of material fact; (3) made with scienter; (4) on which the plaintiff justifiably relied; (5) that proximately caused the alleged loss. *See Binder v. Gillespie*, 184 F.3d 1059, 1063 (9th Cir. 1999). Additionally, as in all actions alleging fraud, plaintiffs must state with particularity the circumstances constituting fraud. Fed. R. Civ. P. 9(b).

C. Section 20(a)

Section 20(a) of the Securities Exchange Act ("Exchange Act") provides derivative liability for those who control others found to be primarily liable under the Act. *In re Ramp Networks, Inc. Sec. Lit.*, 201 F. Supp. 2d 1051, 1063 (N.D. Cal. 2002). Where a plaintiff asserts a section 20(a) claim based on an underlying violation of section 10(b), the pleading requirements for both violations are the same. *Id.*

D. Private Securities Litigation Reform Act

In 1995, Congress enacted the PSLRA to provide "protections to discourage frivolous [securities] litigation." H.R. Conf. Rep, No 104-369, 104th Cong., 1st Sess. at 32 (1995)) [sic] (Nov. 28, 1995). The PSLRA strengthened the pleading requirements of Rules 8(a) and 9(b). Actions based on allegations of material misstatements or omissions under the PSLRA must "specify each statement alleged to have been misleading, the reason or reasons why the statement is misleading, and, if an allegation regarding the statement or omission is made on information and belief, the complaint shall state with particularity all facts on which that belief is formed." 15 U.S.C. §78u-4(b)(1).

The PSLRA also heightened the pleading threshold for causes of action brought under Section 10(b) and Rule 10b-5. Specifically, the PSLRA imposed strict requirements for pleading scienter. A complaint under the PSLRA must "state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind." 15 U.S.C. § 78u-4(b)(2). The Ninth Circuit, in interpreting the PSLRA, has held that "a private securities plaintiff proceeding under the [PSLRA] must plead, in great detail, facts that constitute strong circumstantial evidence of deliberately reckless or conscious misconduct." *In re Silicon Graphics Inc.*, 183 F.3d 970, 974 (9th Cir. 1999). If the complaint does not satisfy the pleading requirements of the PSLRA, upon motion by the defendant, the court, must dismiss the complaint. *See* 15 U.S.C. §78u-4(b)(1).

## ANALYSIS

After the Court dismissed Plantiffs' CAC, Plaintiffs filed the TAC on March 11, 2005. The TAC alleges new facts, upon which Plaintiffs now primarily rely. Plaintiffs once again rely upon three theories to support their section 10(b) action: 1) Defendants' statements regarding wholesaler overstocking; 2) the financial impact of the off label marketing scheme; and 3) Defendants' stock sales.[3]

Defendants move the Court to dismiss the TAC with prejudice pursuant to the PSLRA and Federal Rules of Civil Procedure 9(b), and 12(b)(6) on several

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[3] As Plaintiffs have added no new allegations regarding wholesaler overstocking or stock sales, the Court need not address these allegations again. Thus, the Court will focus only upon the allegations involving the alleged off-label marketing scheme.

grounds. Defendants argue that: 1) Plaintiffs fail to adequately allege that Defendants illegally marketed Viread and that material illegal sales resulted from any such marketing; 2) Plaintiffs fail to allege fraud as to the wholesaler inventory estimate; and 3) Plaintiffs fail to adequately allege the element of loss causation.

A. Falsity and Scienter

To avoid having their action dismissed, Plaintiffs must "plead with particularity either the alleged misleading statements or scienter[.]" *In re Fritz Cos. Sec. Litig.*, 282 F. Supp. 2d 1105, 1112 (N.D. Cal 2003). The Ninth Circuit has articulated the rule as follows:

> Because falsity and scienter in private securities fraud cases are generally strongly inferred from the same set of facts, we have incorporated the dual pleading requirements of 15 U.S.C. §§ 78u-4(b)(1) and (b)(2) into a single inquiry. In considering whether a private securities fraud complaint can survive dismissal under Rule 12(b)(6), we must determine whether particular facts in the complaint, taken as a whole, raise a strong inference that defendants intentionally or deliberate recklessness made false or misleading statements to investors. Where pleadings are not sufficiently particularized or where, taken as a whole, they do not raise a "strong inference" that misleading statements were knowingly or deliberate recklessness made to investors, a private securities fraud complaint is properly dismissed under Rule 12(b)(6).

*Ronconi v. Larkin*, 253 F.3d 423, 429 (9th Cir. 2001) (citations and internal quotation marks omitted).

As the Court found in its previous Order, Plaintiffs have adequately alleged that Defendants engaged in an illegal off-label marketing scheme.[4] (Order at 13:14-16.) When the allegations of CW1 and CW2 are considered in light of the FDA's letters to Gilead, it becomes apparent that Plaintiffs have alleged sufficient facts to raise a strong inference that Defendants had knowledge of the company's off-label marketing scheme.

However, the Court previously found that Plaintiffs failed to establish a connection between the Defendants' off-label marketing activities and the 2003 second quarter reports that Plaintiffs allege were false and misleading.[5] In order to remedy that deficiency, the TAC sheds further light upon the extent and impact of the alleged off-label marketing scheme. Specifically, the TAC relies upon the testimony of CW1 and CW2. According to CW1, 75% to 95% of all Viread sales in the United States were the result of off-label marketing. CW1 also alleges that 85% to 95% of his or her $3 million in Viread sales arose from off-label promotion. Similarly, the TAC states that approximately 85% to 90% of CW2's $25 to $35 million in Viread sales were a result of off-label mar-

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[4] Defendants disagree with this ruling, and contend that "the specific marketing identified in the TAC was fully consistent with Viread's label and thus was completely proper." (Defendants' Motion to Dismiss TAC at 16:28-17:1.) The Court is unpersuaded. While the parties dispute the proper interpretation of the FDA's approval of Viread and Viread Package Labeling, the Court finds that this is a purely factual dispute, and hence it is not susceptible to resolution on a Rule 12(b)(6) motion.

[5] In other words, Plaintiffs must allege that Gilead's off-label marketing scheme was a "material fact" that needed to be disclosed to investors along with the 2003 second quarter sales reports. *See* 15 U.S.C § 78u-4(b)(1)(B).

keting. As a result of off-label marketing, Plaintiffs conclude that Gilead's second quarter 2003 domestic Viread sales of $115.6 million were overstated by approximately $95.95 million. Plaintiffs also conclude that Gilead's third quarter 2003 domestic sales of $59.4 million were overstated by approximately $49.3 million.

Additionally, the TAC details the amount of Viread allegedly sold off-label. For example, according to the TAC, HIV patients co-infected with Hepatitis B initially began using Viread in the third quarter of 2002. At that time, only 55% of co-infected patients were allegedly using Viread. By the third quarter of 2003, 72.7% of co-infected patients surveyed were allegedly using Viread. Plaintiffs allege similar facts regarding the pervasiveness of patients using Viread as a first-line therapy. According to the TAC, Viread had an 11.2% market share as a first-line antiretroviral drug in the fourth quarter of 2001 (TAC at ¶161.) However, by the fourth quarter of 2003, Defendants had allegedly increased this market share to 27.45%. (TAC at ¶161.)

In order to connect these sales increases to Defendants' off-label marketing scheme, Plaintiffs allege that several doctors prescribed Viread for off-label purposes and received unsolicited off-label data from Defendants. For example, Plaintiffs allege that an AIDS-specialist treating between 2,000 and 2,500 AIDS patients prescribed Viread off-label and received unsolicited off-label data from Gilead, (TAC at ¶153.) Plaintiffs also allege that two infectious disease specialists in the Southeast United States both began to receive unsolicited advice on using Viread as a first line therapy from Gilead, and then both began using Viread as a first line therapy. (TAC at ¶160.)

After considering the totality of Plaintiffs' allegations, the Court has serious concerns regarding whether Plaintiffs have adequately alleged that the off-label marketing scheme affected Gilead's sales figures during the second and third quarter of 2003 in a "material" sense. To be certain, the allegations of CW1 and CW2, without more, are insufficient to establish "materiality" under the PSLRA.[6] Plaintiffs' remaining allegations generally involve the pervasiveness of the off-label marketing scheme, the percentage of patients that were allegedly prescribed Viread off-label, and the doctors that received off-label material from Gilead. Whether these allegations, when read in conjunction with the testimony of CW1 and CW2, sufficiently constitute a "material" omission is ultimately a close question. However, the Court need not decide that issue because even assuming that Plaintiffs have sufficiently alleged "materiality," there is no question that Plaintiffs have failed to adequately allege loss causation.

B. Loss Causation

Allegations of "loss causation" are a necessary element of a § 10(b) claim. *Dura Pharmaceuticals, Inc. v. Broudo*, 125 S.Ct. 1627, 1631 (2005). The Supreme Court has recently clarified that merely alleging that a misrepresentation caused an inflated purchase price does not, without more, demonstrate loss causation. *Id.* at 1631-32. To "touch upon" an economic loss is insufficient; plaintiffs must demonstrate an

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[6] CW1's "belief' that 75% to 95% of all sales of Viread in the United States were the result of off-label marketing is apparently only based upon CW1's own off-label Viread sales. The fact that a large majority of CW1's own Viread sales resulted from off-label marketing does not raise an inference that *all Viread sales* in the United states resulted from similar means. CW2's allegations are problematic for similar reasons.

actual "causal connection" between the defendant's material misrepresentation and the economic loss suffered. *Id.* at 1633. The Ninth Circuit has held that a plaintiff sufficiently pleads "loss causation" by alleging that there was a steep drop in defendants' stock price upon revelation by the defendants of previously undisclosed facts. *In re Daou Systems Inc.*, 411 F.3d 1006, 1026 (9th Cir. 2005).

Defendants contend that Plaintiffs have failed to allege the element of loss causation. Defendants assert that Plaintiffs' loss causation allegations are flawed because Gilead disclosed the FDA's warning letter on August 7, 2003, but the drop in Gilead's share price did not occur until October 29, 2003. Defendants argue that the drop in the share price was a direct result of Gilead's October 28, 2003 statements, in which Gilead disclosed that its revenues for Viread in the third quarter of 2003 were less than in the previous quarter and that the company's earlier estimate of the level of second quarter inventory stocking by wholesalers had been too low. Thus, Defendants conclude that Plaintiffs have failed to establish a "causal connection" between the disclosure of the FDA's warning letter (containing the off-label marketing allegations) and the stock price drop.

Plaintiffs respond that the FDA warning letter caused Gilead's domestic sales—the overwhelming number of which were allegedly off-label—to substantially decline in comparison to what they would have been had the off-label marketing continued undiscovered. Plaintiffs assert that the sharp decline in Viread sales suggested that doctors—now alerted to Viread's safety problems and more limited approved uses—were less inclined to prescribe Viread. As a result, Plaintiffs contend that Gilead was unable to

continue increasing prescriptions to new patients in line with growth rates of past quarters. Thus, Plaintiffs conclude that Gilead's dismal October 28 sales report, combined with the prior revelations of Gilead's off-label marketing by the FDA, caused Gilead's stock price to drop 12% on October 29.

The Court finds that Plaintiffs' allegations regarding loss causation are simply too attenuated to withstand scrutiny under *Dura*. As an initial matter, the Court notes that none of Gilead's disclosures on or around October 28 directly related in any way to off-label marketing. Rather, the only disclosures about Defendants' off-label marketing occurred when the FDA warning letter became public on August 7, 2003 and again when Defendants filed their 10-Q on August 14, 2003. *See Dura*, 125 S. Ct. at 1634 ("The complaint's failure to claim that [ ] share price fell significantly after the truth became known suggests that the plaintiffs considered the allegation of purchase price inflation alone sufficient."). The record reflects that Gilead stock price actually rose following the public disclosure of the FDA letter and remained unchanged following the August 14 10-Q filing.

While Plaintiffs concede that the October 28 statements only discussed lower than expected sales numbers, they contend that the dismal financial numbers were a direct result of the disclosure of the off-label marketing scheme on August 7. Thus, Plaintiffs conclude they have sufficiently alleged a "causal connection" between the FDA letter and their losses. The Court disagrees. Plaintiffs contention relies upon the theory that doctors stopped prescribing Viread in such large quantities following the disclosure of the FDA letter, and that this change in prescribing patterns led to a drop in prescriptions that did not be-

come apparent until the October earning release. However, this theory is problematic for a very simple reason—the Court is unable to find these allegations in the TAC. As a result, these allegations cannot serve as the basis for denying a motion to dismiss.[7]

Moreover, Plaintiffs contend that the absence of a stock price drop following the disclosure of the FDA letter was a result of investors not suspecting "that almost all of Defendants' domestic sales depended on off-label marketing." (Plaintiffs' Opposition to Motion to Dismiss TAC at 27:20-21.) However, this argument is flawed because the record reflects that investors never actually learned the extent of Defendants' off-label marketing scheme. Neither Defendants, the FDA, nor a third party ever disclosed such information to the investing public.

Thus, when the TAC is analyzed in light of *Dura*, it is evident that Plaintiffs have not adequately alleged proximate causation and economic loss with respect to Gilead's alleged off-label marketing scheme. To be certain, Plaintiffs do not allege that a price drop immediately accompanied the disclosure of the FDA warning letter, and hence the Court is left to speculate as to what portion of the eventual loss, if any, should be attributed to the disclosure or whether the loss was caused by other factors. "But it should not prove burdensome for a plaintiff who has suffered an economic loss to provide defendant with some indication of the loss and the causal connection that the plaintiff has in mind." *Dura*, 125 S. Ct. at 1634. As in

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[7] In any event, this theory is in direct conflict with Gilead's actual disclosures on October 28, 2003, informing the market that new and total prescriptions increased as compared to the second quarter and as compared to the third quarter of the prior year.

*Dura*, Plaintiffs have failed to make such an indication in the TAC. Accordingly, the Court finds that Plaintiffs have failed to adequately plead loss causation.

C. RULE 20(A) LIABILITY

Section 20(a) of the Securities Exchange Act provides derivative liability for those who control others found to be primarily liable under the Act. *In re Ramp Networks, Inc. Sec. Lit.*, 201 F. Supp. 2d 1051, 1063 (N.D. Cal. 2002). Where a plaintiff asserts a section 20(a) claim based on an underlying violation of section 10(b), the pleading requirements for both violations are the same. *Id.*

Here, Plaintiffs assert that the individual Defendants are liable under this section because of an underlying violation of section 10(b). However, because Plaintiffs have failed to adequately plead the underlying 10b-5 violation, the section 20(a) claims must be dismissed as well.

D. DISMISSAL WITHOUT PREJUDICE

Leave to amend under Federal Rule of Civil Procedure 15 should be liberally granted. "Dismissal with prejudice and without leave to amend is not appropriate unless it is clear . . . that the complaint could not be saved by amendment." *Eminence Capital v. Aspeon Inc.*, 316 F.3d 1048, 1053 (9th Cir. 2003) (error to refuse leave to amend in a securities fraud case to allow plaintiff to plead scienter). Here, the Court notes that after the TAC was filed, *Dura* changed Ninth Circuit law with respect to the pleading of loss causation. Leave to amend is warranted where there has been an intervening change in the law. *See Wilcox v. First Interstate Bank, N.A.*, 815 F.2d 522, 530 (9th Cir. 1987). Accordingly, the Court dismisses the TAC without prejudice. The Plaintiffs should file an

amended complaint within thirty (30) days from the date of this Order.

## CONCLUSION

In light of the heightened pleading standards of the PSLRA and the requirements of Federal Rule of Civil Procedure 12(b)(6), the Court GRANTS Defendants' 12(b)(6) motion to dismiss the TAC without prejudice.

IT IS SO ORDERED.

Dated: October 11, 2005

/s/ MARTIN J. JENKINS
MARTIN J. JENKINS
UNITED STATES DISTRICT JUDGE

# APPENDIX D

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF
CALIFORNIA

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No. C 03-4999 MJJ

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In re GILEAD SCIENCES SECURITIES LITIGATION,

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This Document Relates To: ALL ACTIONS

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## AMENDED ORDER *GRANTING* DEFENDANTS' 12(b)(6) MOTION TO DISMISS

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## INTRODUCTION

Before the Court is Gilead Sciences, Inc. ("Gilead"), John C. Martin, John F. Milligan, Mark L. Perry, Norbert W. Bischofberger, Anthony Carrociolo and William A. Lee's ("Defendants") Motion to Dismiss a federal securities fraud action brought against them by a class consisting of all purchasers of Gilead stock between July 14, 2003 and October 28, 2003. Defendants seek an Order dismissing the Consolidated Amended Class Action Complaint ("Amended Complaint") with prejudice under the heightened pleading requirements of the Private Securities Litigation Reform Act of 1995 ("PSLRA") and pursuant to Federal Rules of Civil Procedure 12(b)(6) and 9(b). For the following reasons, Defendants' motion is GRANTED with leave to amend.

## FACTUAL ALLEGATIONS

This motion arises from an Amended Complaint ("Comp.") alleging securities fraud in violation of section 10(b) of the Securities Exchange Act and Rule 10b-5 promulgated thereunder against all Defendants, and violation of section 20(a) of the Securities Exchange Act. The Amended Complaint is brought on behalf of a class consisting of all persons who purchased or otherwise acquired Gilead stock between July 14, 2003 and October 28, 2003.

The allegations of Plaintiffs' complaint relate to Gilead's announcement in July 2003 of its financial results for the second quarter of 2003, and the impact its premier product, Viread, had on those results Viread is a groundbreaking antiretroviral drug used to treat HIV/AIDS that was introduced in 2001. On July 14, 2003, the first day of the class period, Gilead issued a press release entitled "Gilead Sciences Expects Second Quarter 2003 Financial Results Will Exceed Expectations," and stating, "[t]he increase in revenue was driven primarily by strong sales growth of Viread." The press release went on to say that Viread sales increased due to "broader prescribing patterns . . . as well as increases in U.S. wholesaler inventory levels in the second quarter." On the same day, *Bloomberg News* identified Gilead spokeswoman Amy Flood as stating that "[t]he main reason for the jump in Viread sales is an increase in prescriptions, not inventory stocking."

Two weeks later, on July 31, 2003, Gilead issued a press release containing its final results for the second quarter. Gilead announced that it had net revenues of $230.7 million for the quarter, of which $167 million related to Viread. Gilead went on:

> Viread sales growth was primarily driven by higher prescription volume, a significant increase in U.S. wholesaler inventories and a favorable European currency environment compared to the same quarter last year. Gilead estimates that increased stocking by U.S. wholesalers accounted for $25-30 million in Viread sales in the second quarter.

The press release contained warnings regarding the forward-looking statements and stated that the statements were "subject to certain risks and uncertainties, which could cause actual results to differ materially." Statements made during Gilead's earnings call of that same date, as well as on its Form 10-Q filed August 14, 2003, contained similar warnings.

Also on July 31, 2003, Gilead held a conference call with analysts and other investors regarding its financial results. During the call, an officer of Gilead stated:

> Of significant note, we believe that a substantial inventory build occurred in U.S. distributor channel during the second quarter as wholesalers anticipated the Viread price increase announced on June 27th. Though difficult to determine the exact figure for this inventory build, we estimate that wholesaler inventories increased by $25 to $30 million during the quarter . . . . Based on the U.S. inventory build up seen in the second quarter, we anticipate Viread sales for the third quarter will be at or below the sales level recognized this second quarter. We expect these inventories to be drawn down to more normal levels during this quarter.

On August 14, 2003, Gilead filed its Form 10-Q for the second quarter of 2003. This form confirmed the previously announced financial results. The Form 10-Q also discussed the inventory buildup: "We estimate that this higher stocking resulted in $25.0 to $30.0 million of additional sales during the second quarter, which may adversely impact sales in the third quarter as wholesalers return to more normal inventory levels and buying patterns." The form 10-Q also disclosed the existence of a July 19, 2003 letter issued by the FDA warning Gilead about certain aspects of its promotional practices of Viread.

On October 28, 2003, Gilead announced its financial results for the third quarter of 2003. Gilead announced net revenues of $194.1 million, and sales of Viread of $115.4 million. At that time, Gilead stated: "After reviewing NDC prescription trends, IMS inventory data and actual Viread sales, Gilead estimates there was approximately $33 to $37 million of inventory reduction by U.S. pharmaceutical wholesalers during the third quarter of 2003 following an equivalent inventory build during the second quarter of 2003." The next day, Gilead's stock dropped $7.46 per share from $59.46 per share to close at $52 per share. Approximately one month later, on December 2, 2003, Gilead's stock price had recovered the entire drop experienced on October 29 and closed at $59.83 per share.

Plaintiffs allege that for the period of at least September 2001 through, and subsequent to, the class period, Gilead engaged in the off-label marketing of Viread. Off-label marketing refers to the use for marketing purposes of information such as the result of clinical studies and other materials on the uses of and the efficacy of an FDA-approved product

that has not been approved by the FDA for inclusion in the product's package labeling. Pursuant to FDA guidelines, pharmaceutical manufacturers such as Gilead may only promote an FDA-approved drug consistent with the contents of its FDA-approved package labeling.

Plaintiffs allege that Gilead's off-label marketing activities began as early as September 2001 at Gilead's national sales meeting in Miami. There, sales and marketing employees allegedly were given information regarding Gilead's submission of Viread clinical data and information to the FDA and, with a "wink and a nod," were instructed to use this information to sell Viread even though Viread had yet to be approved by the FDA. The FDA approved Viread in October, 2001. Later, employees allegedly were instructed at numerous regional and national sales meetings by Gilead executives "overtly and covertly," to use off-label information to aggressively promote and sell Viread. At these meetings, employees allegedly would be provided off-label information such as updates on clinical trials of Viread in large group meetings and then told in subsequent smaller meetings to use this information to sell Viread. Defendants Martin, Perry, Lee, Milligan, and Bischofberger allegedly attended one or more of these regional and national sales meetings.

According to the Amended Complaint, Gilead received an Untitled FDA Letter on March 14, 2002, advising the company that its representatives had made false and misleading oral promotional statements at the December 2001 Interscience Conference on Antimicrobial Agents and Chemotherapy conference. According to the Untitled FDA Letter, Gilead falsely and misleadingly promoted Viread by stating

that it contained "no toxicities," was "extremely safe," and was "extremely well-tolerated," despite the fact that its boxed warning and Package Labeling advised to the contrary. The Untitled FDA Letter further ordered Gilead to "immediately cease making such violative statements," and required Gilead to submit a written response describing its intent and plans to comply with the FDA's directives. Plaintiff alleges that the false statements were made by Defendant Martin and it was company-wide knowledge that Martin was the cause of the Untitled FDA Letter. On March 21, 2002, Gilead responded stating that it was "commit[ted] to ensure that future violative statements are not made in the promotion of Viread." However, sixteen months later, on July 29, 2003, the FDA issued a second letter, notifying Gilead that it considered certain oral representations made by a Gilead representative at a promotional booth during a conference in April 2003 to be improper. This conference took place during Gilead's second fiscal quarter of 2003, just prior to Defendants' first class period announcement of outstanding Viread sales and financial results which exceeded market expectations. In response to and in compliance with this letter, on November 7, 2003, defendant Martin wrote a correction letter to the conference's attendees.

JUDICIAL NOTICE

In addition to the Motion to Dismiss the Amended Complaint, Defendants have filed a Request for Judicial Notice, and ask the Court to notice a number of documents. Federal Rule of Evidence 201 allows a court to take judicial notice of a fact "not subject to reasonable dispute in that it is . . . capable of accurate and ready determination by resort to sources whose accuracy can not reasonably be questioned."

Plaintiffs do not object to the Court's taking judicial notice of the requested documents.[1]

A. Documents Explicitly Referenced in the Amended Complaint

Initially, Defendants ask the Court to take judicial notice of specified press releases, one news article, and SEC filings explicitly referenced in the Amended Complaint under the "incorporation by reference" doctrine. This doctrine permits the Court to consider documents alleged in a complaint and whose authenticity no party questions, but which are not physically attached to [plaintiffs'] pleading." *Branch v. Tunnell*, 14 F.3d 449, 454 (9th Cir. 1994). Here, this includes press releases dated July 14 and July 31, 2003, a news article dated July 14, 2003, and Gilead's Form 10-Q filed with the SEC, all of which are attached to the Declaration of Grant Fondo and explicitly referenced in the Amended Complaint. Plaintiffs do not dispute the authenticity of any of these documents, or claim that Defendants documents contain errors. Absent such an argument, incorporation under *Branch* is warranted.

B. Allegations on Which the Complaint Implicitly Rely

The Court can take judicial notice of Exhibit D because "the Court may take judicial notice of documents on which allegations in the [complaint] necessarily rely, even if not expressly referenced in the [complaint], provided the authenticity of those documents is not in dispute," *In re Calpine Corp. Sec.*

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[1] However, Plaintiffs object to Defendants' Motion for Judicial Notice only if Defendants seek to have the Court take judicial notice of the truth of the requested documents. The Court does not restrict its taking of judicial notice in this way.

*Litig*, 288 F. Supp. 2d 1054, 1076 (N.D. Cal. 2003). Plaintiffs necessarily rely upon this conference call because they claim that Defendants perpetuated a fraud on the market with the July 31, 2003 financial announcement and estimated inventory build-up. Therefore, the statements made in the conference call directly relate to the claim of fraud on the market and the transcript reflects information available to the market at the time.

C. Public Filings With the SEC

Defendants ask the Court to take judicial notice of publically available documents that Defendants filed with the SEC. "In a securities action, a court may take judicial notice of public filings when adjudicating a motion to dismiss . . . ." *Calpine*, 288 F. Supp. 2d at 1076. Accordingly, the Court takes judicial notice of these documents.[2]

LEGAL STANDARDS

A. Rule 12(b)(6)

A court may dismiss a complaint pursuant to Federal Rule of Civil Procedure 12(b)(6) for either lack of a cognizable legal theory or the pleading of insufficient facts under an adequate theory. *Robertson v. Dean Witter Reynolds, Inc.*, 749 F.2d 530, 533-34 (9th Cir. 1984). When deciding upon a motion to dismiss for failure to state a claim upon which relief can be granted pursuant to FRCP 12(b)(6), a court must take all of the material allegations in plaintiff's complaint as true, and construe them in the light most favorable to plaintiff.

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[2] The Court refuses to take judicial notice of Ex. O (April 2003 press release), as it does not fit into any of the recognized categories allowing for judicial notice.

*Parks School of Business, Inc, v. Symington*, 51 F.3d 1480, 1484 (9th Cir. 1995). Moreover, a complaint should not be dismissed unless a plaintiff could prove no set of facts in support of his claim that would entitle him to relief. *Id.*

In the context of a motion to dismiss, review is limited to the contents in the complaint. *Allarcom Pay Television, Ltd v. General Instrument Corp.*, 69 F.3d 381, 385 (9th Cir. 1995). When matters outside the pleading are presented to and accepted by the court, the motion to dismiss is converted into one for summary judgment. Where such a conversion takes place, all parties must be given an opportunity to present all material made pertinent to such a motion by Rule 56. *In re Pacific Gateway Exchange, Inc. Sec. Lit.*, 169 F. Supp. 2d 1160, 1164 (N.D. Cal 2001); *see also* Fed. R. Civ. P. 12(b). However, matters properly presented to the court, such as those attached to the complaint and incorporated within its allegations, may be considered as part of the motion to dismiss. *See Hal Roach Studios, Inc. v. Richard Feiner & Co.*, 896 F.2d 1542, 1555 n.19 (9th Cir. 1989).

Where a plaintiff fails to attach to the complaint documents referred to in it, and upon which the complaint is premised, a defendant may attach to the motion to dismiss such documents in order to show that they do not support plaintiff's claim. *See Pacific Gateway Exchange*, 169 F. Supp. 2d at 1164; *Branch v. Tunnell*, 14 F.3d 449, 44 [sic] (9th Cir. 1994), *cert denied*, 512 U.S. 1219 (1997). Thus, the district court may consider the full texts of documents that the complaint only quotes in part. *See In re Stay Electronics Sec. Lit.*, 89 F.3d 1399, 1405 n.4 (1996), *cert denied*, 520 U.S. 1103 (1997). This rule precludes plaintiffs "from surviving a Rule 12(b)(6) motion by

deliberately omitting references to documents upon which their claims are based." *Parrino v. FHP, Inc.*, 146 F.3d 699, 705 (9th Cir. 1998).

B. Section 10(b) and Rule 10b-5

Section 10(b) of the Securities Exchange Act provides, in part, that it is unlawful "to use or employ in connection with the purchase or sale of any security registered on a national securities exchange or any security not so registered, any manipulative or deceptive device or contrivance in contravention of such rules and regulations as the [SEC] may prescribe." 15 U.S.C. § 78j(b).

Rule 10b-5 makes it unlawful for any person to use interstate commerce

(a) To employ any device, scheme, or artifice to defraud.

(b) To make any untrue statement of material fact or to omit to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading, or

(c) To engage in any act, practice, or course of business which operates or would operate as a fraud or deceit upon any person, in connection with the purchase or sale of any security.

17 C.F.R. § 240.10b-5.

To be actionable under section 10(b) and Rule 10b-5, a plaintiff must allege (1) a misrepresentation or omission; (2) of material fact; (3) made with scienter; (4) on which the plaintiff justifiably relied; (5) that proximately caused the alleged loss. *See Binder v.*

*Gillespie*, 184 F.3d 1059, 1063 (9th Cir. 1999), Additionally, as in all actions alleging fraud, plaintiffs must state with particularity the circumstances constituting fraud. Fed. R. Civ. P. 9(b).

C. Section 20(a)

Section 20(a) of the Securities Exchange Act ("Exchange Act") provides derivative liability for those who control others found to be primarily liable under the Act. *In re Ramp Networks, Inc. Sec. Lit.*, 201 F. Supp. 2d 1051, 1063 (N.D. Cal. 2002). Where a plaintiff asserts a section 20(a) claim based on an underlying violation of section 10(b), the pleading requirements for both violations are the same. *Id.*

D. Private Securities Litigation Reform Act

In 1995, Congress enacted the PSLRA to provide "protections to discourage frivolous [securities] litigation." H.R. Conf. Rep. No. 104-369, 104th Cong., 1st Sess. at 32 (1995)) [sic] (Nov. 28, 1995). The PSLRA strengthened the pleading requirements of Rules 8(a) and 9(b). Actions based on allegations of material misstatements or omissions under the PSLRA must "specify each statement alleged to have been misleading, the reason or reasons why the statement is misleading, and, if an allegation regarding the statement or omission is made on information and belief, the complaint shall state with particularity all facts on which that belief is formed." 15 U.S.C. §78u-4(b)(1).

The PSLRA also heightened the pleading threshold for causes of action brought under Section 10(b) and Rule 10b-5. Specifically, the PSLRA imposed strict requirements for pleading scienter. A complaint under the PSLRA must "state with particularity facts giving rise to a strong inference that the defendant

acted with the required state of mind." 15 U.S.C. § 78u-4(b)(2). The Ninth Circuit, in interpreting the PSLRA, has held that "a private securities plaintiff proceeding under the [PSLRA] must plead, in great detail, facts that constitute strong circumstantial evidence of deliberately reckless or conscious misconduct." *In re Silicon Graphics Inc.*, 183 F.3d 970, 974 (9th Cir. 1999). If the complaint does not satisfy the pleading requirements of the PSLRA, upon motion by the defendant, the court must dismiss the complaint. *See* 15 U.S.C, §78u-4(b)(1)

ANALYSIS

In order to support its claims under the PLSRA, Plaintiffs must first specify a "statement alleged to have been misleading." 15 U.S.C. § 78u-4(b)(1). Plaintiffs argue that statements from four separate incidents attributed to Defendants were false and misleading.[3]

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[3] Before engaging in the pertinent legal analysis, the Court deems it necessary to highlight the theory of Plaintiffs' action. In their original complaint, Plaintiffs alleged that Defendants gave a false impression of the true demand for Viread by understating the degree to which drug wholesalers had increased their inventory levels. To that end, Plaintiffs' complaint focused primarily upon Defendants' July 31, 2003, estimate of inventory stocking numbers ($25 to $30 million) and Defendants' revision of those numbers on October 28, 2003 ($30 to $37 million). In fact, nearly all of the statements that Defendants allege were false involve Gilead's public statements regarding its estimate of the impact inventory stocking had on the company's second quarter financial results. This is evidenced by the fact that Plaintiffs' class period began on July 14, 2003 and ended on October 28, 2003.

However, Plaintiffs' Amended Complaint alleged new facts, upon which Plaintiffs now primarily rely. Plaintiffs contend that Defendants engaged in improper off-label marketing of Viread

Initially, Plaintiffs contend that statements from Gilead's press release on July 14, 2003 were false. Specifically, the press release stated that "[t]he increase in revenue was driven primarily by strong sales growth of Viread." The press release went on to state that Viread sales increased due to "broader prescribing patterns . . . as well as increases in U.S. wholesaler inventory level in the second quarter in anticipation of a Viread price increase." On the same day, the *Bloomberg News* identified Gilead spokeswoman Amy Flood as stating that "[t]he main reason for the jump in Viread sales is an increase in prescriptions, not inventory stocking." Plaintiffs also assert that this statement was false and misleading.

Next, Plaintiffs allege that Gilead's July 31, 2003 press release contained false statements. In the press release, the company stated that "Viread sales growth was primarily driven by higher prescription volume, a significant increase in U.S. wholesaler inventories and a favorable European currency environment . . . . Gilead estimates that increased stocking by U.S. wholesalers accounted for $25-30 million of Viread sales in the second quarter." The

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that lead to increased Viread prescriptions. Consequently, Plaintiffs allege that Viread's 2003 second quarter sales report overstated the true demand for the drug. Plaintiff assert that Defendants violated the PSLRA by not disclosing the off-label marketing profits, as these profits were material adverse facts necessary to make the company's second quarter statement not misleading. In their Opposition to Defendants' Motion to Dismiss, Plaintiffs allege that Gilead's misrepresentations regarding overstocking, in combination with the company's off-label marketing scheme, "support an inference that Defendants knew, or were deliberately reckless in ignoring, that the Company materially understated its reports of sales to wholesalers in Second Quarter 2003."

press release also stated that the company was "focused on continuing this sales momentum and increasing our market share through robust clinical data and label expansions . . . ." Plaintiffs assert that these statements were false.

Finally, Plaintiffs assert that Gilead's Second Quarter 2003 10-Q contained false statements. Specifically, the company stated that "[t]he increase in product sales is due to the significant increase in the volume of sales of Viread." The Second Quarter 2003 10-Q also stated that "[t]he significant increase in Viread sales is due to increased prescription volume."

Defendants move the Court to dismiss the Amended Complaint with prejudice pursuant to the PSLRA and Federal Rules of Civil Procedure 8(a), 8(e), 9(b), and 12(b)(6) on several grounds. Defendants argue that: 1) Plaintiffs fail to plead facts with the required particularity that Defendants' public statements were false and misleading at the time they were made; 2) the Amended Complaint fails to plead scienter; 3) the Safe Harbor provisions of the Reform Act bars claims based on Defendants' forward looking statements; 4) Plaintiffs fail to plead that defendants Martin, Milligan, Perry, Bischofberger, Carraciolo, and Lee are liable as control persons under section 20(a) of the Exchange Act.

A. Falsity and Scienter

In order to avoid having their action dismissed, Plaintiffs must "plead with particularity either the alleged misleading statements or scienter[.]" *In re Fritz Cos. Sec. Litig.*, 282 F Supp. 2d 1105, 1112 (N.D. Cal 2003). The Ninth Circuit has articulated the rule as follows:

> Because falsity and scienter in private securities fraud cases are generally strongly inferred from the same set of facts, we have incorporated the dual pleading requirements of 15 U.S.C §§ 78u-4(b)(1) and (b)(2) into a single inquiry. In considering whether a private securities fraud complaint can survive dismissal under Rule 12(b)(6), we must determine whether particular facts in the complaint, taken as a whole, raise a strong inference that defendants intentionally or deliberate recklessness made false or misleading statements to investors, Where pleadings are not sufficiently particularized or where, taken as a whole, they do not raise a "strong inference" that misleading statements were knowingly or deliberate recklessness made to investors, a private securities fraud complaint is properly dismissed under Rule 12(0(6).

*Ronconi v. Larkin*, 253 F.3d 423, 429 (9th Cir. 2001) (citations and internal quotation marks omitted).

*1. Defendants' Misrepresentations Regarding Wholesaler Overstocking*

Defendants argue that Plaintiffs have not pointed to any evidence to indicate that any of Defendants' statements regarding wholesaler overstocking were false or misleading. Defendants assert that Gilead's increase in revenues in the second quarter of 2003, was in fact, driven by strong sales of Viread. Defendants also assert that the growth in Viread sales was driven by higher prescription volumes and an increase in wholesaler inventories. Defendant also contend that their estimate of the inventory stocking numbers in July of 2003 ($25 to $30 million) was based on the best available data at the time. In essence, Defendants assert that the statements chal-

lenged by Plaintiffs were not false, misleading, or even equivocal, but were in fact entirely true.

Plaintiffs contend that the Amended Complaint adequately details the manner in which Defendants materially understated Viread sales to wholesalers in the July 31 press release. Plaintiffs argue that the "significant shift in wholesaler sales from $25 to $30 million to $33 to $37 million" is strong evidence that Defendants' estimates were misleading. Plaintiffs also argue that the difference between the estimates is "material" and must be considered by the Court. Regarding Defendants' other challenged statements, Plaintiffs assert that given the announced price increase of Viread, Defendants must have known that Gilead's higher second quarter sales figures were related to increased inventory stocking of Viread, and not increased prescription sales.

The Court finds that Plaintiffs have failed to allege any facts inconsistent with the conclusion that Gilead's 2003 second quarter financial reports were made in good faith and based on the best information available at the time. Most importantly, Plaintiffs have not referenced a single document or conversation suggesting Defendants knew that the July 31 estimate of the second quarter inventory stocking numbers was too low at the time the estimate was made public. It is noteworthy that the press release contained only an "estimate" of the increased stocking numbers, and the press release specifically warned investors of Gilead's limited ability to accurately estimate inventory levels. In fact, the press release stated that Gilead was making a "great deal of assumptions" and "rely[ing] on incomplete data" in making the estimate. Moreover, as noted by Defendants, Gilead's revised October estimates re-

garding increased stocking numbers were not significantly different than the original July estimate. Additionally, Plaintiffs have not alleged facts that would tend to show that the growth in Viread sales was not driven, at least in part, by higher prescription sales.[4] Given these considerations, the Court finds that Plaintiffs have not alleged sufficient facts to demonstrate that any of Defendants' statements regarding wholesaler overstocking were false or misleading at the time the statements were made,

*2. Off-Label Marketing Scheme*

While not conceding the issue of wholesaler stocking, Plaintiffs spend the majority of their Opposition to Defendants' Motion to Dismiss focusing on Gilead's alleged off-label marketing scheme. Plaintiffs allege that the off-label marketing scheme was "the cornerstone of [Gilead's] business." Plaintiffs conclude that Defendants had a duty to disclose the details of the off-label marketing scheme, and the subsequent FDA warning letters, to its investors.[5] According to Plain-

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[4] In a similar case to this one, the plaintiffs had alleged that the Company's executives knew that wholesaler purchases of a pharmaceutical company's product in one quarter would lead to overstocking and, therefore, would result in fewer sales in the next quarter, while at the same time defendants were publically projecting strong future sales. *Lipton v. Pathogenesis Corp.*, 284 F.3d 1027 (9th Cir. 2002). The court found that the complaint's reference to internal reports on sales data and patient demand data was insufficient to support a PSLRA claim. *Id.* at 1036. "Plaintiffs do not mention a specific [ ] document relied on by defendants such as a particular [ ] report, graph or chart. Nor do they detail with particularity the content of such data." *Id.* Here, Plaintiffs have not referenced a single internal report on Gilead's sales data that could have provided information (scienter) to Defendants.

[5] Thus, it appears that Plaintiffs are bringing their action pursuant to 15 U.S.C. § 78u-4(b)(1)(B), which instructs Plain-

tiffs, Defendants' off-label marketing enabled the company to create the appearance of increased prescriptions and demand for Viread. As a result, wholesalers were encouraged to stock up on Viread ahead of Gilead's announced price increase. Plaintiffs further allege that Gilead's second quarter sales estimates, including wholesaler stocking, were tainted by the off-label marketing scheme because the marketing "created an artificial and illusory demand for Viread."

Defendants argue that Plaintiffs never allege that anyone at Gilead (including Defendants) actually participated in improper off-label marketing activities. Defendants also contend that Plaintiffs have not shown a connection between Gilead's alleged off-label marketing activities and actual sales of Viread.

The Court initially considers whether Plaintiffs have adequately alleged that Defendants engaged in an illegal off-label marketing scheme. The Amended Complaint states that Plaintiffs' confidential witnesses (CW1 and CW2) attended various meetings at which Gilead's sales and marketing team received specific instructions to market Viread off-label. Specifically, according to the Amended Complaint, CW1 and CW2 attended the 2002 Los Angeles Regional Meeting at which Defendants Meyers, Perry, and Martin were in attendance. A similar meeting took place in Las Vegas during 2003 and Defendants Milligan, Perry, Bischofberger, and Martin were allegedly present. Additionally, a company meeting took place in Orlando during 2003, and CW 1 and

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tiffs to allege that Defendants "omitted to state a material fact necessary in order to make the statements made, in light of the circumstances in which they were made, not misleading."

CW 2 recall that Defendants Martin, Milligan, Bischofberger, Lee, and Perry were in the room when specific instructions were given to sales and marketing personnel to utilize off-label information to push sales of Viread. Moreover, both CW1 and CW2 attended various other meetings, not attended by Defendants, in which Gilead presenters provided off-label information and encouraged them to use the information to sell Viread.

In addition to the allegations of CW1 and CW2, the Court must consider the FDA letters that were sent to Gilead. The March 14, 2002 letter advised Gilead that its promotional activities were violating the Federal Food, Drug, and Cosmetic Act. These violations arose from "false and misleading oral statements about Viread" made by Viread representatives in Chicago during 2001. The letter advised Gilead to "immediately cease making such violative statements and . . . cease . . . distribution or use of any promotional materials for Viread that contain violative . . . . statements." The FDA sent another letter to Gilead on July 29, 2003, and stated that Gilead representatives had "minimized important risk information and broadened the indication for Viread." As a result of these violations, the FDA instructed Gilead to provide the agency with a detailed response regarding its promotional activities of Viread.

Defendants contend that CW 1 and CW 2 never allege that Defendants actually participated in improper off-label marketing activities. Defendants are correct. Indeed, CW1 and CW 2 only allege that Gilead representatives were instructed to engage in such activity, not that such activity actually took place. However, the Court must also consider the FDA letters sent to Gilead. In those letters, the FDA

clearly confirms that Gilead representatives were actively engaging in the off-label marketing of Viread with the intent to increase Viread sales. Therefore, when the allegations of CW1 and CW2 are considered in light of the FDA's letters to Gilead, it becomes apparent that Plaintiffs have alleged sufficient facts to raise a strong inference that Defendants' had knowledge of the company's off-label marketing scheme.

Yet, this conclusion does not end the Court's inquiry. Plaintiffs must also establish a connection between the company's off-label marketing activities and the 2003 second quarter reports that Plaintiffs allege were false and misleading. In other words, Plaintiffs must allege that Gilead's off-label marketing scheme was a "material fact" that needed to be disclosed to investors along with the 2003 second quarter sales reports.[6] *See* 15 U.S.C. § 78u-4(b)(1)(B). Plaintiffs have not carried this burden. Specifically, Plaintiffs have not alleged that any sales of Viread during the second quarter of 2003 were the result of improper off-label marketing activities. In fact, Plaintiffs do not identify a single prescription written for Viread that was allegedly generated by off-label marketing activity. Under the heightened pleading standard required in PSLRA cases, the Court cannot simply assume that Gilead's off-label marketing of

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[6] It is noteworthy that the July 29, 2003 warning letter from the FDA was disclosed to the public on August 7, 2003, and referenced in Gilead's second quarter Form 10-Q filed with the SEC on August 14, 2003. Interestingly, the record reveals that the public announcement of the FDA letter did not have an adverse affect on Gilead's stock price. This fact weighs against a finding that Defendants' off-label marketing scheme was a "material fact" requiring disclosure to investors.

Viread necessarily resulted in increased sales of that drug. Instead, Plaintiffs must allege facts to bridge this logical gap. Plaintiffs have failed to do so.

Furthermore, even assuming Plaintiffs had alleged that such sales took place, Plaintiffs would also have to allege that those sales were "material" to the 2003 second quarter reports. While Plaintiffs may not be required to detail the impact of Viread's off-label marketing on a sale-by-sale basis, Plaintiffs must allege facts that show a relationship between the off-label marketing of Viread, related sales of Viread, and the manner in which those sales affected Gilead's 2003 second quarter financial reports. Plaintiffs have alleged no such facts.

*3. Stock Sales*

Plaintiffs also rely on stock sales by the individual Defendants as an indication of their scienter. Generally, stock sale allegations can not raise an inference of scienter unless Plaintiffs allege specific facts showing that the sales were "dramatically out of line with prior trading practices at times calculated to maximize the personal benefit from undisclosed inside information." *Silicon Graphics*, 183 F.3d at 986. Among the relevant factors for a court to consider are: 1) the amount and percentage of shares sold by insiders; 2) timing of the sales; and 3) whether the sales were consistent with the insider's prior trading history. *Id.*

Defendant Martin sold 50,000 shares of Gilead stock, 2.62% of his total shares, during the class period. Defendant Bischofberger sold 90,020 shares, 9.47% of his total shares, during the class period. Defendant Perry sold 52,344 shares, 10.95% of his total shares, during the class period. Defendant Lee

sold 15,000 shares, 4.03% of his total shares, during the class period. Defendant Milligan sold 11,000 shares, 5.45% of his total shares, during the class period. Defendant Carraciolo sold 324,601 shares, 100% of his total shares, during the class period.

In light of the three factors above, these sales are not sufficiently suspicious to raise an inference of scienter. Other than Mr. Carraciolo, none of the individual defendants sold more than eleven percent of their holdings in Gilead during the class period.[7] *See Ronconi*, 253 F.3d at 435 (suggesting that sales of 10-17% of holdings was not suspicious). Collectively, the individual defendants sold just over eight percent of their share. Moreover, with the exception of Mr. Carraciolo, the individual defendants sold a roughly proportional number of shares in the third quarter of 2003 (the class period) as in the second quarter of 2003. Such sales are not sufficiently suspicious.

Plaintiffs allege that the timing of the stock sales are suspicious because Defendants Perry and Bischofberger sold their stock during the first week of August 2003, before the company disclosed that it had received a warning letter from the FDA. The Court disagrees. These sales represent only a small percentage of the total sales the Plaintiffs allege are

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[7] Even though Mr. Carraciolo sold 100% of his shares in Gilead, his sales represent a relatively insignificant portion of the allegedly suspicious sales. It is also relevant that Mr. Carraciolo had become a company officer on July 30, 2003, and thus the Court has no context in which to infer that Mr. Carraciolo's sales were suspicious. *See Silicon Graphics*, 183 F.3d at 987 ("And although [defendant] had never sold such a large quantity of stock, he had only been with [the company] for a year and had no significant trading history for purposes of comparison.").

suspicious. *See Ronconi*, 253 F.3d at 435 (stating that when corporate insiders collectively fail to seize a prime opportunity to "gain[ ] market advantage from as yet undisclosed bad news," an inference of scienter is negated). Therefore, the Court also does not find the timing of the stock sales suspicious.

*4. Allegations as a Whole*

In sum, the Amended Complaint "lacks sufficient detail and foundation necessary to meet either the particularity or strong inference requirements of the PSLRA." *Silicon Graphics*, 183 F.3d at 984. In *No. 84 Employer-Teamster Joint Council Pension Trust Fund v. America West Holding Corp.*, 320 F.3d 920 (9th Cir. 2003), the plaintiffs alleged that officers of America West Airlines had artificially inflated the company's stock prices. In support of their case, the plaintiffs alleged specific omissions and misrepresentations by the company's officers regarding deferred maintenance costs, unsafe maintenance practices, an ongoing investigation by the Federal Aviation Administration, and highly suspicious stock sales, in which most of the individual defendants sold 100% of their shares. *Id.* at 938-42. Viewing the totality of the allegations, the court held that the plaintiffs "raise[d] a strong inference that Defendants knew that the maintenance problems were ongoing and, thus, that the statements made by America West were false." *Id.* at 942.

Unlike the situation in *America West*, Plaintiffs have failed to allege particularized facts that could lead the Court to infer that Defendants knowingly misrepresented the details of Gilead's 2003 second quarter sales numbers. Even when the alleged misrepresentations regarding wholesaler stocking are considered together with the off-label marketing scheme

and the challenged stock sales, Plaintiffs have failed to set forth adequate corroborating details and facts to support their allegations under the PSLRA pleading standard.[8] *See America West*, 320 F.3d at 945 (holding that the allegations must be considered to their totality in determining whether plaintiffs have met the PSLRA standard).

RULE 20(a) LIABILITY

Section 20(a) of the Securities exchange Act provides derivative liability for those who control others found to be primarily liable under the Act. *In re Ramp Networks, Inc. Sec. Lit.*, 201 F. Supp. 2d 1051, 1063 (N.D. Cal. 2002). Where a plaintiff asserts a section 20(a) claim based on an underlying violation of section 10(b), the pleading requirements for both violations are the same. *Id.*

Here, Plaintiffs assert that the individual Defendants are liable under this section because of an underlying violation of section 10(b). However, because Plaintiffs have failed to adequately plead the underlying 10b-5 violation, the section 20(a) claims must be dismissed as well.

DISMISSAL WITHOUT PREJUDICE

Leave to amend under Federal Rule of Civil Procedure 15 should be liberally granted. "Dismissal with prejudice and without leave to amend is not appropriate unless it is clear . . . that the complaint could not be saved by amendment." *Eminence Capital v. Aspeon Inc.*, 316 F.3d 1048, 1053 (9th Cir. 2003)

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[8] Since Plaintiffs have not met the PSLRA pleading standard, the Court does not need to decide whether Defendants' statements fall within the safe harbor provision under 15 U.S.C. § 78u-5(c)(1)(A) or (B).

(error to refuse leave to amend in a securities fraud case to allow plaintiff to plead scienter). Here, it is possible that Plaintiffs could remedy their significant pleading defects in an amended complaint by adding detailed factual support for their allegations of false or misleading statements, and demonstrating that Defendants had the requisite scienter at the time the statements were made. Accordingly, the Court dismisses the Amended Complaint without prejudice. The Plaintiffs should file an amended complaint within thirty (30) days from the date of this Order.

## CONCLUSION

After consideration of the Amended Complaint in light of the heightened pleading standards of the PSLRA and the requirements of Federal Rule of Civil Procedure 12(b)(6), the Court GRANTS Defendants' 12(b)(6) motion to dismiss without prejudice.

IT IS SO ORDERED.

Dated: January 26, 2005

/s/
MARTIN J. JENKINS
UNITED STATES DISTRICT JUDGE

## APPENDIX E

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

[Filed OCT. 9, 2008]

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No. 06-16185
D.C. No. CV-03-04999-MJJ
Northern District of California, San Francisco

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In re: GILEAD SCIENCES SECURITIES LITIGATION.

RICK HARTMAN, on behalf of himself and all others similarly situated; TRENT ST. CLARE; TERRY JOHNSON,
*Plaintiff-Appellants*,

v.

GILEAD SCIENCES, INC.; JOHN C. MARTIN; JOHN F. MILLIGAN; MARK L. PERRY; NORBERT W. BISCHOFBERGER; ANTHONY CARRACIOLO; and WILLIAM LEE,
*Defendants-Appellees*.

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ORDER

Before: KOZINSKI, Chief Judge, HAWKINS, and COWEN,* Circuit Judges.

The panel has voted to deny the petition for rehearing. Chief Judge Kozinski and Judge Hawkins have voted to deny the petition for rehearing en banc. Judge Cowen has recommended denying the en banc petition.

The full court has been advised of the petition for rehearing en banc and no Judge has requested a vote

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* The Honorable Robert E. Cowen, Senior United States Circuit Judge for the Third Circuit, sitting by designation.

on whether to rehear the matter en banc. Fed. R. App. P. 35.

The petition for rehearing and petition for rehearing en banc are DENIED.